Exhibit A

THE UNITED STATES DISTRICT COURT
DISTRICT OF SOUTH CAROLINA
CHARLESTON DIVISION

Michael Masiowski, M.D. on behalf of himself and all others similarly situated,

Plaintiff,

AMERISOURCEBERGEN DRUG CORPORATION; CARDINAL HEALTH, INC.; McKESSON CORPORATION; PURDUE PHARMA L.P.; PURDUE PHARMA, INC.; THE PURDUE FREDERICK COMPANY, INC.; TEVA PHARMACEUTICAL INDUSTRIES, LTD.; TEVA PHARMACEUTICALS USA, INC.; CEPHALON, INC.; JOHNSON & JOHNSON; JANSSEN PHARMACEUTICALS, INC.; ORTHOMCNEIL-JANSSEN PHARMACEUTICALS, INC. n/k/a JANSSEN PHARMACEUTICALS, INC.; JANSSEN PHARMACEUTICA INC. n/k/a JANSSEN PHARMACEUTICALS, INC.; NORAMCO, INC.; ENDO HEALTH SOLUTIONS INC.; ENDO PHARMACEUTICALS, INC.; ALLERGAN PLC f/k/a ACTAVIS PLS; WATSON PHARMACEUTICALS, INC. n/k/a ACTAVIS, INC.; WATSON LABORATORIES, INC.; ACTAVIS LLC; ACTAVIS PHARMA, INC. f/k/a WATSON PHARMA, INC.; INSYS THERAPEUTICS, INC. MALLINCKRODT PLC and MALLINCKRODT LLC.,

Defendants.

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CASE NO.: 2:18-cv-02080-MDL
CLASS ACTION COMPLAINT
JURY TRIAL DEMANDED

CLASS ACTION COMPLAINT

Plaintiff, Michael Masiowski, M.D., an emergency room physician, on behalf of himself and all others similarly situated, brings this Complaint against Defendants Purdue Pharma L.P.; Purdue Pharma, Inc.; The Purdue Frederick Company, Inc.; Teva Pharmaceutical Industries, LTD.; Teva Pharmaceuticals USA, Inc.; Cephalon, Inc.; Johnson & Johnson; Janssen Pharmaceuticals, Inc.; Ortho-McNeil-Janssen Pharmaceuticals, Inc. n/k/a Janssen Pharmaceuticals, Inc.; Janssen Pharmaceutica Inc. n/k/a Janssen Pharmaceuticals, Inc.; Noramco, Inc.; Endo Health Solutions Inc.; Endo Pharmaceuticals, Inc.; Allergan PLC f/k/a Actavis PLS; Watson Pharmaceuticals, Inc. n/k/a Actavis, Inc.; Watson Laboratories, Inc.; Actavis, LLC; Actavis Pharma, Inc. f/k/a Watson Pharma, Inc.; Insys Therapeutics, Inc.; Mallinckrodt plc; Mallinckrodt LLC; McKesson Corporation; Cardinal Health, Inc.; and AmerisourceBergen Drug Corporation (collectively "Defendants") and allege as follows:

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INTRODUCTION

1. This case is about one thing: corporate greed. Defendants put their desire for profits above the health and well-being of consumers, and emergency room physician health care providers at the cost to Plaintiff and the putative class of emergency room physicians that he seeks to represent.

2. Tens of thousands of patients have been treated by emergency room physicians because of the "opioid epidemic" throughout the United States.

3. Plaintiff and the putative class lost millions of dollars each year in providing emergency room health care services to patients who were uninsured, were indigent (i.e. lacked resources to pay for the services), or otherwise eligible for services through programs such as Medicaid. These payments were at below market rates. All of these services to be referred to as "Opioid Treatment Services" were necessary for Plaintiff and the putative class to provide because of the adverse effects to patients from prescription opium painkillers ("opioids") which are manufactured, marketed, promoted, sold, and/or distributed by the Defendants.

4. Plaintiff and the putative class, in essence, have been forced to provide an inordinate amount of emergency room services related to the "opioid epidemic," either for no compensation or for compensation substantially below market rates.

5. Substance use disorders are a spectrum that range from misuse and abuse of drugs to addiction.[1] Throughout this Complaint, "addiction" refers to the entire range of

[1] Diagnostic and Statistical Manual of Mental Disorders (5th ed. 2013) ("DSM-V").

substance abuse disorders. Individuals suffer negative consequences wherever they fall on the substance use disorder spectrum.

6. Defendants knew that opioids were effective treatments for only short-term post-surgical and trauma-related pain, and for palliative (end-of-life) care. Yet they also knew—and had known for years—that opioids were highly addictive and subject to abuse, particularly when used long- term for chronic non-cancer pain (pain lasting three months or longer, hereinafter referred to as "chronic pain"), and should there not be used except as a last-resort.

7. Defendants knew that, barring exceptional circumstances, opioids were too addictive and too debilitating for long-term use for chronic non-cancer pain lasting three months or longer.

8. Defendants further knew—and had known for years—that with prolonged use, the effectiveness of opioids wanes, requiring increases in doses and markedly increasing the risk of known significant side effects and addiction.[2,3]

9. Defendants also knew that controlled studies on the safety and efficacy of opioids were limited to short-term use (not longer than 90 days), and in managed settings (*e.g.*, hospitals), where the risk of addiction and other adverse outcomes was much less significant.

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[2] *See, e.g.*, Russell K. Portenoy, Opioid Therapy for Chronic Nonmalignant Pain: Current Status, 1 Progress in Pain Res. & Mgmt. 247 (1994).

[3] The authoritative Diagnostic and Statistical Manual of Mental Disorders, (5th ed. 2013) ("DSM-V") "substance use disorders" are a spectrum that ranges from misuse and abuse of drugs to addiction. Patients suffer negative consequences wherever they fall on the substance use disorder continuum. Throughout this Complaint, "addiction" refers to this range of substance use disorders..

10. Indeed, the U.S. Food and Drug Administration ("FDA") has expressly recognized that there have been no long-term studies demonstrating the safety and efficacy of opioids for long-term use.[4]

11. Prescription opioids, which include well-known brand-name drugs like OxyContin and Percocet, and generics like oxycodone and hydrocodone; are narcotics. They are derived from or possess properties similar to opium and heroin, which is why they are regulated as controlled substances.[5] Like heroin, prescription opioids work by binding to receptors on the spinal cord and in the brain, dampening the perception of pain. Opioids also can create a euphoric high, which can make them addictive. At certain doses, opioids can slow the user's breathing, causing respiratory depression and death.

12. Defendants' success in extending the market for opioids to new patients and chronic conditions has created an abundance of drugs available for criminal use and fueled a new wave of addiction, abuse, and injury. Defendants' scheme supplies both ends of the secondary market for opioids—producing both the inventory of narcotics to sell and the addicts to buy them. One researcher who has closely studied

[4] Letter from Janet Woodcock, M.D., Dir., Ctr. for Drug Eval. & Res., to Andrew Kolodny, M.D., Pres. Physicians for Responsible Opioid Prescribing, Re Docket No. FDA-2012-P-0818 (Sept. 10, 2013).

[5] Since passage of the Controlled Substances Act ("CSA") in 1970, opioids have been regulated as controlled substances. As controlled substances, they are categorized in five schedules, ranked in order of their potential for abuse, with Schedule I being the most dangerous. The CSA imposes a hierarchy of restrictions on prescribing and dispensing drugs based on their medicinal value, likelihood of addiction or abuse, and safety. Opioids generally had been categorized as Schedule II or Schedule III drugs. Schedule II drugs have a high potential for abuse, have a currently accepted medical use, and may lead to severe psychological or physical dependence. Schedule III drugs are deemed to have a lower potential for abuse, but their abuse still may lead to moderate or low physical dependence or high psychological dependence.

the public health consequences of opioids has found, not surprisingly, that a "substantial increase in the nonmedical use of opioids is a predictable adverse effect of substantial increases in the extent of prescriptive use."[6] It has been estimated that the majority of the opioids that are abused come, directly or indirectly, through doctors' prescriptions.

13. A significant black market in prescription opioids also has arisen, not only creating and supplying additional addicts, but fueling other criminal activities.

14. In addition, because heroin is cheaper than prescription painkillers, many prescription opioid addicts migrate to heroin. Self-reported heroin use nearly doubled between 2007 and 2012, from 373,000 to 669,000 individuals. In 2010, more than 3,000 people in the U.S. died from heroin overdoses, also nearly double the rate in 2006. Nearly 80% of those who used heroin in the past year had previously abused prescription opioids. Patients become addicted to opioids and then move on to heroin because these prescription drugs are roughly four times more expensive than heroin on the street. In the words of one federal DEA official, "Who would have ever thought in this country it would be cheaper to buy heroin than pills . . . [t]hat is the reality we're facing."[7]

15. According to addiction programs, a typical course sees addicts requesting more and more opioids from their doctors, who eventually cut them off. Many addicts then

[6] G. Caleb Alexander et al., Rethinking Opioid Prescribing to Protect Patient Safety and Public Health, 308(18) JAMA 1865 (2012).
[7] Matt Pearce & Tina Susman, Philip Seymour Hoffman's death calls attention to rise in heroin use, L.A. Times, Feb. 3, 2014, http://articles.latimes.com/2014/feb/03/nation/la-na-heroin-surge-20140204 (accessed July 17, 2018).

doctor-shop for additional prescriptions, and when that source runs out, turn to the streets to buy opioids illicitly. A significant number become heroin addicts. Addiction treatment programs, whose patient populations vary, reported rates of patients who had switched from prescription opioids to heroin ranging from half to 95%. Those addicts who do reach treatment centers often do so when their health, jobs, families and relationships reach the breaking point, or after turning to criminal activity such as prostitution and theft to sustain their addiction. Unfortunately, few are successful in getting and staying clean; repeated relapse is common.

16. In order to expand the market for opioids and realize blockbuster profits, Defendants, through the use of unfair and deceptive practices, created a sea of change in the medical and public perception that the use of opioids not just safe and effective for acute and palliative care, but also for long periods to treat more common aches and pains, like lower back pain, arthritis, and headaches.

17. Defendants, through a sophisticated, highly deceptive and unfair marketing campaign that began in the late 1990s, deepened around 2006, and continues to the present, set out to, and did, reverse the popular and medical understanding of opioids. Chronic opioid therapy—the prescribing of opioids to treat chronic pain long-term—is now commonplace.

18. To accomplish this reversal, Defendants spent hundreds of millions of dollars:

    a. developing and disseminating seemingly truthful scientific and educational materials and advertising that misrepresented the risks, benefits, and superiority of opioids long-term use to treat chronic pain;

b. deploying sales representatives who visited doctors and other prescribers and delivered misleading messages about the use of opioids;

c. recruiting prescribing physicians as paid speakers as a means to secure those physicians' future "brand loyalty" and extend their reach to all physicians;

d. funding, assisting, encouraging, and directing certain doctors, known as "key opinion leaders" ("KOLs"), not only to deliver scripted talks, but also to draft misleading studies, present continuing medical education programs ("CMEs") that were deceptive and lacked balance, and serve on the boards and committees of professional societies and patient advocacy groups that delivered messages and developed guidelines supporting chronic opioid therapy; and

e. funding, assisting, directing, and encouraging seemingly neutral and credible professional societies and patient advocacy groups (referred to hereinafter as "Front Groups") that developed educational materials and treatment guidelines that were then distributed by Defendants, which urged doctors to prescribe, and patients to use, opioids long-term to treat chronic pain.

19. These efforts, executed, developed, supported, and directed by Defendants, were designed not to present a fair view of how and when opioids could be safely and effectively used, but rather to convince doctors, patients, and others that the benefits of using opioids to treat chronic pain outweighed the risks and that opioids could be used safely by most patients. Defendants and the third parties whom they recruited and supported, all profited handsomely through their dissemination of the deceptive

information. KOLs and Front Groups saw their stature in the medical community elevated dramatically due to Defendants' funding, and Defendants saw an equally dramatic rise in their revenues.

20. Working individually, with, and through these Front Groups and KOLs, Defendants pioneered a new and far broader market for their potent and highly addictive drugs—the chronic pain market. Defendants persuaded doctors, patients, and others that what they had long understood—that opioids are addictive drugs and unsafe in most circumstances for long-term use—was untrue, and to the contrary, that the compassionate treatment of pain *required* opioids. Ignoring the limitations and cautions in their own drugs' labels, Defendants:

    a. overstated the benefits of chronic opioid therapy, promised improvement in patients' function and quality of life, and failed to disclose the lack of evidence supporting long-term use;

    b. trivialized or obscured their serious risks and adverse outcomes, including the risk of addiction, overdose, and death;

    c. overstated their superiority compared with other treatments, such as other non-opioid analgesics, physical therapy, and other alternatives;

    d. mischaracterized the difficulty of withdrawal from opioids and the prevalence of withdrawal symptoms. There was, and is, no competent or reliable scientific evidence to support Defendants' marketing claims, and there was, and is, a wealth of competent and reliable scientific evidence that these claims are simply false; and

e. deceptively and unfairly marketed the drugs for indications and benefits that were outside of the drugs' labels and not supported by substantial evidence.

21. Even Defendants' KOLs initially were very cautious about whether opioids were appropriate to treat chronic pain. Some of these same KOLs have since recanted their pro-opioid marketing messages and acknowledged that Defendants' marketing went too far. Yet despite the voices of renowned pain specialists, researchers, and physicians who have sounded the alarm on the overprescribing of opioids to treat chronic pain, Defendants continue to disseminate their misleading and unfair marketing claims to this day.

22. Defendants' efforts were wildly successful in expanding opioid abuse. The United States is now awash in opioids. In 2012, health care providers wrote 259 million prescriptions for opioid painkillers—enough to medicate every adult in America around the clock for a month. Twenty percent of all doctors' visits in 2010 resulted in the prescription of an opioid, nearly double the rate in 2000. Opioids—once a niche drug—are now the most prescribed class of drugs—more than blood pressure, cholesterol, or anxiety drugs. While Americans represent only 4.6% of the world's population, they consume 80% of the opioids supplied around the world and 99% of the global hydrocodone supply.

23. Together, opioids generated $8 billion in revenue for drug companies in 2012. Of that amount, $3.1 billion went to Purdue for its OxyContin sales. By 2015, sales of opioids grew further to approximately $9.6 billion.[8]

[8] D. Crow, Drugmakers hooked on $10bn opioid habit, Financial Times (August 10, 2016) available at https://www.ft.com/content/f6e989a8-5dac-11e6-bb77-a121aa8abd95 (accessed July 17, 2018).

24. It was Defendants' false marketing—and not any medical breakthrough—that rationalized prescribing opioids for chronic pain and opened the floodgates of opioid use and abuse. The result has been catastrophic.

25. Indeed, the National Institutes of Health ("NIH") not only recognizes the opioid abuse problem, but also identifies Defendants' "aggressive marketing" as a major cause: "Several factors are likely to have contributed to the severity of the current prescription drug abuse problem. They include drastic increases in the number of prescriptions written and dispensed, greater social acceptability for using medications for different purposes, and *aggressive marketing by pharmaceutical companies*."[9]

26. There is a direct correlation between the sales of opioids and deaths and hospitalizations caused by opioids:[10]

27. According to the U.S. Centers for Disease Control and Prevention ("CDC"), the nation has been swept up in an opioid-induced "public health epidemic."[11] According to the CDC, prescription opioid use contributed to 16,651 overdose deaths nationally in 2010; 16,917 in 2011; and 16,007 in 2012. One Defendant's own 2010 internal data shows that it knew that the use of prescription opioids gave rise to 40% of drug-related emergency department visits in 2010 and 40% of drug poisoning deaths in 2008, and

[9] America's Addiction to Opioids: Heroin and Prescription Drug Abuse. Available at http://www.drugabuse.gov/about-nida/legislative-activities/testimony-to-congress/2015/americas-addiction-to-opioids-heroin-prescription-drug-abuse#_ftn2 (accessed July 12, 2018) (*emphasis added*).

[10] The Prescription Opioid and Heroin Crisis: A Public Health Approach to an Epidemic of Addiction, Annu. Rev. Public Health 2015, accessed at http://www.annualreviews.org/doi/pdf/10.1146/annurev-publhealth-031914-122957 (accessed July 12, 2018)

[11] CDC, Examining the Growing Problems of Prescription Drug and Heroin Abuse (Apr. 29, 2014), http://www.cdc.gov/washington/testimony/2014/t20140429.htm (accessed July 12, 2018)

that the trend of opioid poisonings was increasing from 1999-2008. For every death, more than 30 individuals are treated in emergency rooms.

28. According to the CDC, more than 12 million Americans age 12 or older have used prescription painkillers without a prescription in 2010, [12] and adolescents are abusing opioids in alarming numbers.

29. Opioid abuse has not displaced heroin, but rather triggered a resurgence in its use, imposing additional burdens on the County and local agencies that address heroin use and addiction. According to the CDC, the percentage of heroin users who also use opioid pain relievers rose from 20.7% in 2002-2004 to 45.2% in 2011-2013. Heroin produces a very similar high to prescription opioids, but is often cheaper. While a single opioid pill may cost $10-$15 on the street, users can obtain a bag of heroin, with multiple highs, for the same price. It is hard to imagine the powerful pull that would cause a law-abiding, middle-aged person who started on prescription opioids for a back injury to turn to buying, snorting, or injecting heroin, but that is the dark side of opioid abuse and addiction.

30. As a direct result of the opioid and eventual heroin epidemic more than 17,000 Americans died from prescription opioids in 2015 and the number continues to steadily grow.[13]

31. Statistics from the CDC found that in 2015, opioids were responsible for over 33,000 deaths nationwide.[14]

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[12] CDC, Prescription Painkiller Overdoses in the US (Nov. 2011), https://www.cdc.gov/vitalsigns/painkilleroverdoses/ (accessed July 12, 2018).
[13] https://www.bloomberg.com/news/articles/2017-06-28/life-after-opioids-drugmakers-scramble-to-concoct-alternatives (accessed July 12, 2018)
[14] Executive Order 2017-146 (2017). Available at http://www.flgov.com/wp-

32. Defendants' actions are not permitted or excused by the fact that their labels (with the exception of Cephalon's labels for Fentora and Actiq) may have allowed, or did not exclude, the use of opioids for chronic non-cancer pain. The FDA's approval did not give Defendants license to misrepresent the risks, benefits, or superiority of opioids. Indeed, what makes Defendants' efforts particularly nefarious—and dangerous—is that, unlike other prescription drugs marketed unlawfully in the past, opioids are highly addictive controlled substances. Defendants deceptively and unfairly engaged a patient base that—physically and psychologically—could not turn away from their drugs, many of whom were not helped by the drugs or were profoundly damaged by them.

33. Nor is Defendants' causal role broken by the involvement of doctors. Defendants' marketing efforts were both ubiquitous and highly persuasive; their deceptive messages tainted virtually every source doctors could rely on for information and prevented them from making informed treatment decisions. Defendants targeted not only pain specialists, but also primary care physicians (PCPs), nurse practitioners, physician assistants, and other non-pain specialists who were even less likely to be able to assess the companies' misleading statements. Defendants were also able to callously manipulate what doctors wanted to believe—namely, that opioids represented a means of relieving their patients' suffering and of practicing medicine more compassionately.

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content/uploads/orders/2017/EO_17-146.pdf (accessed July 12, 2018). *See also*, Executive Orders 2017-177 and 2017-230 (2017).

34. The National Institutes of Health ("NIH") not only recognizes the opioid abuse problem, but also identifies Defendants' "aggressive marketing" as a major cause: "Several factors are likely to have contributed to the severity of the current prescription drug abuse problem. They include drastic increases in the number of prescriptions written and dispensed, greater social acceptability for using medications for different purposes, and *aggressive marketing by pharmaceutical companies*."[15] As shown below, the "drastic increases in the number of prescriptions written and dispensed" and the "greater social acceptability for using medications for different purposes " are not really independent causative factors but are in fact the direct result of "the aggressive marketing by pharmaceutical companies."

35. The rising numbers of persons addicted to opioids have led to an increase in health care services that Plaintiff and the putative class he seeks to represent must provide for no compensation or below-market rate compensation. Specifically Plaintiff, and the putative class he seeks to represent must deal with the consequences of a major increase in issues such as drug abuse, diversion,[16] and crimes related to obtaining opioid medications. Plaintiff and the putative class he seeks to represent have been severely and negatively impacted due to the fraudulent misrepresentations and omissions by Defendants regarding the use and risk related to opioids. In fact, upon information and belief, Defendants have been and continue to be aware of the high levels of diversion of their product.

[15] America's Addiction to Opioids: Heroin and Prescription Drug Abuse. Available at http://www.drugabuse.gov/about-nida/legislative-activities/testimony-to-congress/2018/americas-addiction-to-opioids-heroin-prescription-drug-abuse (accessed July 12, 2018) (emphasis added).

[16] The CDC defines using or obtaining opioids illegally as "diversion."

36. As a direct and foreseeable consequence of Defendants' wrongful conduct, Plaintiff and the putative class he seeks to represent have been required to provide millions of dollars of services for no compensation or substantially reduced compensation at below market rates. Plaintiff has incurred and continues to incur costs related to opioid addiction and abuse, including, but not limited to, substantial loss of appropriate compensation for increased emergency and medical care services and lost productivity costs. Defendants' misrepresentations regarding the safety and efficacy of long-term opioid use proximately caused injury to Plaintiff and the class that he seeks to represent.

37. In sum, Plaintiff and the putative class that he seeks to represent have experienced economic costs directly related to the opioid epidemic, including substantial loss of income for having to provide emergency room medical services for either no compensation or payment substantially below market rates.

PARTIES

38. Plaintiff, Michael Masiowski, M.D. is an emergency room physician who independently practiced in Charleston County in South Carolina as early as April of 2000.

Manufacturer Defendants

39. The Manufacturer Defendants are defined below. At all relevant times, the Manufacturer Defendants have packaged, distributed, supplied, sold, placed into the stream of commerce, labeled, described, marketed, advertised, promoted and purported to warn or purported to inform prescribers and users regarding the benefits and risks associated with the use of the prescription opioid drugs. The Manufacturer Defendants, at all times, have

manufactured and sold prescription opioids without fulfilling their legal duty prevent diversion and report suspicious orders.

40. PURDUE PHARMA L.P. is a limited partnership organized under the laws of Delaware. PURDUE PHARMA INC. is a New York corporation with its principal place of business in Stamford, Connecticut, and THE PURDUE FREDERICK COMPANY is a Delaware corporation with its principal place of business in Stamford, Connecticut (collectively, "Purdue").

41. Purdue manufactures, promotes, sells, and distributes opioids in the United States and South Carolina, including the following:

    a. OxyContin (oxycodone hydrochloride extended release) is a Schedule II opioid agonist[17] tablet first approved in 1995 and indicated for the "management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate." Prior to April 2014,[18] OxyContin was indicated for the "management of moderate to severe pain when a continuous,

[17] An opioid agonist is a drug that activates certain opioid receptors in the brain. An antagonist, by contrast, blocks the receptor and can also be used in pain relief or to counter the effect of an opioid overdose.

[18] The labels for OxyContin and other long-acting opioids were amended in response to a 2012 citizens' petition by doctors. The changes were intended to clarify the existing obligation to "make an individualized assessment of patient needs." The petitioners also successfully urged that the revised labels heighten the requirements for boxed label warnings related to addiction, abuse, and misuse by changing "Monitor for signs of misuse, abuse, and addiction" to "[Drug name] exposes users to risks of addiction, abuse, and misuse, which can lead to overdose and death." Letter from Bob Rappaport, Dir. Ctr. for Drug Evaluations & Res., Labeling Supplement and PMR [Post-Marketing Research] Required (Sept. 10, 2013), http://www.fda.gov/downloads/Drugs/DrugSafety/InformationbyDrugClass/UCM367697.pdf (accessed July 12, 2018).

around-the- clock opioid analgesic is needed for an extended period of time."

b. MS Contin (morphine sulfate extended release) is a Schedule II opioid agonist tablet first approved in 1987 and indicated for the "management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate." Prior to April 2014, MS Contin was indicated for the "management of moderate to severe pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time."

c. Dilaudid (hydromorphone hydrochloride) is a Schedule II opioid agonist first approved in 1984 (injection) and 1992 (oral solution and tablet) and indicated for the "management of pain in patients where an opioid analgesic is appropriate."

d. Dilaudid-HP (hydromorphone hydrochloride) is a Schedule II opioid agonist injection first approved in 1984 and indicated for the "relief of moderate-to- severe pain in opioid-tolerant patients who require larger than usual doses of opioids to provide adequate pain relief."

e. Butrans (buprenorphine) is a Schedule III opioid partial agonist transdermal patch first approved in 2010 and indicated for the "management of pain severe enough to require daily, around- the-clock, long-term opioid treatment and for which

alternative treatment options are inadequate." Prior to April 2014, Butrans was indicated for the "management of moderate to severe pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time."

f. Hysingla ER (hydrocodone bitrate) is a Schedule II opioid agonist tablet first approved in 2014 and indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.

g. Targiniq ER (oxycodone hydrochloride and naloxone hydrochloride) is a Schedule II combination product of oxycodone, an opioid agonist, and naloxone, an opioid antagonist, first approved in 2014 and indicated for the management of pain severe enough to require daily, around- the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.

42. OxyContin is Purdue's best-selling opioid. Since 2009, Purdue's annual nationwide sales of OxyContin have fluctuated between $2.47 billion and $2.99 billion, up four-fold from its 2006 sales of $800 million. OxyContin constitutes roughly 30% of the entire market for analgesic drugs (painkillers).

43. CEPHALON, INC. is a Delaware corporation with its principal place of business in Frazer, Pennsylvania.

44. TEVA PHARMACEUTICAL INDUSTRIES, LTD. ("Teva Ltd.") is an Israeli corporation with its principal place of business in Petach Tikva, Israel. In 2011, Teva Ltd. acquired Cephalon, Inc. TEVA PHARMACEUTICALS USA, INC. ("Teva USA") is a Delaware corporation which is a wholly owned subsidiary of Teva Ltd. In Pennsylvania. Teva USA acquired Cephalon in October of 2011.

45. Cephalon has been in the business of manufacturing, selling, and distributing the following opioids, in the United States and South Carolina:

    a. Actiq (fentanyl citrate) is a Schedule II opioid agonist lozenge (lollipop) first approved in 1998 and indicated for the "management of breakthrough cancer pain in patients 16 years of age and older who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain."

    b. Fentora (fentanyl citrate) is a Schedule II opioid agonist buccal tablet (similar to plugs of smokeless tobacco) first approved in 2006 and indicated for the "management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain."

46. In 2008, Cephalon pled guilty to a criminal violation of the Federal Food, Drug and Cosmetic Act for its misleading promotion of Actiq and two other drugs, and agreed to pay $425 million.[19]

[19] Press Release, u.s. Dep't of Justice, Biopharmaceutical Company. Cephalon, to Pay $425 Million & Enter Plea to Resolve Allegations of Off-Label Marketing (Sept. 29, 2008), https://www.justice.gov/archive/opa/pr/2008/September/08-civ-860.html (last accessed Jul. 12, 2018).

47. Teva Ltd., Teva USA, and Cephalon, Inc. work together closely to market and sell Cephalon products in the United States. Teva Ltd. conducts all sales and marketing activities for Cephalon in the United States through Teva USA and has done so since its October of 2011 acquisition of Cephal on. Teva Ltd. and Teva USA hold out Actiq and Fentora as Teva products to the public. Teva USA sells all former Cephalon branded products through its "specialty medicines" division. The FDA-approved prescribing information and medication guide, which is distributed with Cephalon opioids, discloses that the guide was submitted by Teva USA, and directs physicians to contact Teva USA to report adverse events.

48. All of Cephalon's promotional websites, including those for Actiq and Fentora, display Teva Ltd.'s logo.[20] Teva Ltd.'s financial reports list Cephalon's and Teva USA's sales as its own, and its year-end report for 2012 - the year immediately following the Cephalon acquisition- attributed a 22% increase in its specialty medicine sales to "the inclusion of a full year of Cephalon's specialty sales," including *inter alia* sales of Fentora®.[21] Through interrelated operations like these, Teva Ltd. operates in the United States through its subsidiaries Cephalon and Teva USA. The United States is the largest of Teva Ltd.'s global markets, representing 53% of its global revenue in 2015, and, were it not for the existence of Teva USA and Cephalon, Inc., Teva Ltd. would conduct those companies' business in the United States itself. Upon information and belief, Teva Ltd. directs the business practices of Cephalon and Teva USA, and their profits inure to the benefit of

[20] *E.g.*, ACTIQ, http://www.actiq.com/ (displaying logo at bottom-left) (accessed July 12, 2018).
[21] Teva Ltd., Annual Report (Form 20-F) 62 (Feb. 12, 2013), http://annualreports.com/HostedData/AnnualReportArchive/t/NASDAQ_TEVA_2012.pdf (accessed July 13, 2018)

Teva Ltd. as controlling shareholder. Teva Pharmaceutical Industries, Ltd., Teva Pharmaceuticals USA, Inc., and Cephalon, Inc. are referred to as "Cephalon."

49. JANSSEN PHARMACEUTICALS, INC. is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey, and is a wholly owned subsidiary of JOHNSON & JOHNSON (J&J), a New Jersey corporation with its principal place of business in New Brunswick, New Jersey. NORAMCO, INC. ("Noramco") is a Delaware company headquartered in Wilmington, Delaware and was a wholly owned subsidiary of J&J until July of 2016. ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., now known as JANSSEN PHARMACEUTICALS, INC., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. JANSSEN PHARMACEUTICA INC., now known as JANSSEN PHARMACEUTICALS, INC., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. J&J is the only company that owns more than 10% of Janssen Pharmaceuticals' stock, and corresponds with the FDA regarding Janssen's products. Upon information and belief, J&J controls the sale and development of Janssen Pharmaceuticals' drugs and Janssen's profits inure to J&J's benefit. Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica, Inc., Noramco, and J&J are referred to as "Janssen."

50. Janssen manufactures, promotes, sells, and distributes drugs in the United States, including the opioid Duragesic (fentanyl). Before 2009, Duragesic accounted for at least $1 billion in annual sales.

51. Until January 2015, Janssen developed, marketed, and sold the following opioids in the United States and South Carolina:

a. Nucynta ER (tapentadol extended release) is a Schedule II opioid agonist tablet first approved in 2011 and indicated for the "management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate." Prior to April 2014, Nucynta ER was indicated for the "management of moderate to severe chronic pain in adults [and] neuropathic pain associated with diabetic peripheral neuropathy (DPN) in adults." The DPN indication was added in August 2012.

b. Nucynta (tapentadol) is a Schedule II opioid agonist tablet and oral solution first approved in 2008 and indicated for the "relief of moderate to severe acute pain in patients 18 years of age or older."

52. Together, Nucynta and Nucynta ER accounted for $172 million in sales in 2014.

53. ENDO HEALTH SOLUTIONS INC. is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. ENDO PHARMACEUTICALS INC. is a wholly owned subsidiary of Endo Health Solutions Inc. and is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. Endo Health Solutions, Inc. and Endo Pharmaceuticals Inc. are referred to as "Endo."

54. Endo develops, markets, and sells prescription drugs, including the opioids in the United States and South Carolina including:

a. Opana ER (oxymorphone hydrochloride extended release) is a Schedule II opioid agonist tablet first approved in 2006 and indicated for the "management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate." Prior to April 2014, Opana ER was indicated for the "relief of moderate to severe pain in

patients requiring continuous, around-the-clock opioid treatment for an extended period of time." On June 8, 2017, the FDA requested that Endo Pharmaceuticals remove its opioid medication, reformulated Opana ER (oxymorphone hydrochloride), from the market.[22]

b. Opana (oxymorphone hydrochloride) is a Schedule II opioid agonist tablet first approved in 2006 and indicated for the "relief of moderate to severe acute pain where the use of an opioid is appropriate."

c. Percodan (oxycodone hydrochloride and aspirin) is a Schedule II opioid agonist tablet first approved in 1950 and first marketed by Endo in 2004 and indicated for the "management of moderate to moderately severe pain."

d. Percocet (oxycodone hydrochloride and acetaminophen) is a Schedule II opioid agonist tablet first approved in 1999 and first marketed by Endo in 2006 and indicated for the "relief of moderate to moderately severe pain."[23]

55. Opioids made up roughly $403 million of Endo's overall revenues of $3 billion in 2012. Opana ER yielded $1.15 billion in revenue from 2010 and 2013, and it accounted for 10% of Endo's total revenue in 2012. Endo also manufactures and sells generic opioids such as oxycodone, oxymorphone, hydromorphone, and hydrocodone products in the United States, by itself and through its subsidiary, Qualitest Pharmaceuticals, Inc.

[22] FDA Requests Removal of Opana ER for Risks Related to Abuse. https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm562401.htm (last accessed July 12, 2018).

[23] In addition, Endo marketed Zydone (hydrocodone bitartrate and acetaminophen), a Schedule III opioid agonist tablet indicated for the "relief of moderate to moderately severe pain," from 1998 through 2013. The FDA's website indicates this product is currently discontinued, but it appears on Endo's own website.

56. ALLERGAN PLC is a public limited company incorporated in Ireland with its principal place of business in Dublin, Ireland. ACTA VIS PLC acquired ALLERGAN PLC in March 2015, and the combined company changed its name to ALLERGAN PLC in January 2013. Before that, WATSON PHARMACEUTICALS, INC. acquired ACTAVIS, INC. in October 2012, and the combined company changed its name to Actavis, Inc. as of January 2013 and then ACTAVIS PLC in October 2013. WATSON LABORATORIES, INC. is a Nevada corporation with its principal place of business in Corona, California, and is a wholly-owned subsidiary of ALLERGAN PLC (f/k/a Actavis, Inc., f/k/a Watson Pharmaceuticals, Inc.). ACTAVIS PHARMA, INC. (f/k/a Actavis, Inc.) is a Delaware corporation with its principal place of business in New Jersey and was formerly known as WATSON PHARMA, INC. ACTAVIS LLC is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey. Each of these defendants is owned by ALLERGAN PLC, which uses them to market and sell its drugs in the United States. Upon information and belief, ALLERGAN PLC exercises control over these marketing and sales efforts and profits from the sale of Allergan/ Actavis products ultimately inure to its benefit. ALLERGAN PLC, ACTAVIS PLC, ACTAVIS, Inc., Actavis LLC, Actavis Pharma, Inc., Watson Pharmaceuticals, Inc., Watson Pharma, Inc., and Watson Laboratories, Inc. are referred to as "Actavis."

57. Actavis manufactures, promotes, sells, and distributes opioids, including the branded drugs Kadian and Norco, a generic version of Kadian, and generic versions of Duragesic and Opana, in the United States and South Carolina. Actavis acquired the rights to Kadian from King Pharmaceuticals, Inc. on December 30, 2008, and began marketing Kadian in 2009.

58. Insys Therapeutics, Inc. (“Insys”) is a Delaware corporation with its principal place of business in Chandler, Arizona.

59. Insys develops, markets, and sells prescription drugs, including Subsys, a sublingual spray of fentanyl, throughout the United States including Charleston County, South Carolina.

60. MALLINCKRODT, PLC is an Irish public limited company headquartered in Staines-upon-Tharnes, United Kingdom, with its U.S. headquarters in St. Louis, Missouri. MALLINCKRODT, LLC is a limited liability company organized and existing under the laws of the State of Delaware. Mallinckrodt, plc and Mallinckrodt, LLC are referred to as "Mallinckrodt."

61. Mallinckrodt manufactures, markets, and sells drugs in the United States and South Carolina including generic oxycodone, of which it is one of the largest manufacturers. In July of 2017 Mallinckrodt agreed to pay $35 million to settle allegations brought by the Department of Justice that it failed to detect and notify the DEA of suspicious orders of controlled substances.

Distributor Defendants

62. The Distributor Defendants also are defined below. At all relevant times, the Distributor Defendants have distributed, supplied, sold, and placed into the stream of commerce the prescription opioids, without fulfilling the fundamental duty of wholesale drug distributors to detect and warn of diversion of dangerous drugs for non-medical purposes. The Distributor Defendants universally failed to comply with federal law. Plaintiff alleges the unlawful conduct by the Distributor Defendants is responsible for the volume of prescription opioids plaguing the United States.

63. McKESSON CORPORATION ("McKesson") is a Delaware corporation, with its principal place of business located in San Francisco, California. McKesson distributes pharmaceuticals to retail pharmacies and institutional providers in all 50 states including South Carolina.

64. CARDINAL HEALTH, INC. ("Cardinal") is an Ohio corporation with its principal place of business located in Dublin, Ohio. Cardinal distributes pharmaceuticals to retail pharmacies and institutional providers in all 50 states including South Carolina..

65. AMERISOURCEBERGEN DRUG CORPORATION ("AmerisourceBergen") is a Delaware corporation with its principal place of business in Chesterbrook, Pennsylvania. AmerisourceBergen distributes pharmaceuticals to retail pharmacies and institutional providers in all 50 states including South Carolina..

JURISDICTION AND VENUE

66. This Court has subject matter jurisdiction under 28 U.S.C. § 1331 based upon the federal claims asserted under the Racketeer Influenced and Corrupt Organizations Act, 18 U.S.C. § 1961, *et seq.* ("RICO"). This Court has supplemental jurisdiction over Plaintiff's state law claims pursuant to 28 U.S.C. § 1367 because those claims are so related to Plaintiff's federal claims that they form part of the same case or controversy.

67. This Court independently has subject matter jurisdiction over Plaintiff's state law claims under 28 U.S.C. § 1332(d)(2)(A), because the matter in controversy, the aggregated claims of the individual Class members, exceeds the sum of five million dollars, exclusive of interest and costs, and Plaintiff is a citizen of a state different from Defendants. Under 28 U.S.C. §1332(d)(5), there are more than 100 members of the proposed class.

68. This Court has jurisdiction over this action pursuant to the provisions of S.C. Code § 36-2-803 in that Defendants, individually or acting by and through their authorized agents, officers, representatives, servants and employees, operated, conducted, transacted business in South Carolina; committed a tortious act within the state; caused tortious injury in the state; producing, manufacturing and/or distributing goods with the reasonable expectation that those goods were to be used or consumed within the state, which were so used and consumed; by, among other things:

    a. Manufacturing, selling and distributing highly addictive prescription opioid drugs in South Carolina while engaging in a pattern and practice of disseminating patently false and misleading information about the safety and efficacy of these opioid drugs;

    b. Intentionally diminishing the associated health hazards of prescription opioid drugs and conspiring with key opinion leaders to increase their sales and profits despite the known risks and dangerous propensity of these drugs;

    c. Consensually submitting to the jurisdiction of South Carolina when obtaining a manufacturer or distributor license; and/or

    d. Owning and/or operating a distribution center in South Carolina that distributes the Defendant manufacturers' prescription opioid drugs to the citizens of South Carolina.

69. Defendants derived substantial revenue as the result of the opioids which were distributed to physicians, patients, and others and later consumed by persons then residing in the United States. Defendants' intentional and tortious conduct is continuing and presently existing, arose out of or is incidental to each Defendant's

interstate, intrastate and international business ventures conducted in the United States, and proximately caused the Plaintiff to sustain losses and damages in the State of South Carolina. Accordingly, the Defendants have the requisite minimum contacts with South Carolina necessary to constitutionally permit this Court to exercise jurisdiction because:

a. The Defendants' contacts with South Carolina, including, but not limited to, their manufacture, sale, distribution and/or promotion of highly addictive prescription opioid drugs, are directly related to and gave rise to this Complaint;

b. Defendants' purposefully availed themselves of the privilege of conducting business in the State of South Carolina by selling, distributing and/or promoting the use of highly addictive prescription opioid drugs to doctors, hospitals, patients, health insurers and other individuals throughout the State of South Carolina, including, but not limited to, Charleston County, South Carolina; and

c. Defendants' fraudulent and deceptive marketing campaign and intentional misconduct was such that the Defendants should have reasonably anticipated being hauled into court in South Carolina.

70. Venue is proper in this District under 28 U.S.C. § 1391(b)(2), because Plaintiff is domiciled in this judicial district, because a substantial part of the events and omissions giving rise to Plaintiff's claims occurred in this judicial district, and under 28 U.S.C. § 1391 (b)(1) and § (c)(2), because all the Defendants are subject to personal jurisdiction in this state and in this judicial district, such that Defendants are deemed to reside in this state and in this judicial district.

FACTUAL ALLEGATIONS

I. THE OPIOID EPIDEMIC

71. The past two decades have been characterized by increasing abuse and diversion of prescription drugs, including opioid medications, in the United States.[24]

72. Prescription opioids have become widely prescribed. By 2010, enough prescription opioids were sold to medicate every adult in the United States with a dose of 5 milligrams of hydrocodone every four (4) hours for one (1) month.[25]

73. By 2011, the U.S. Department of Health and Human Resources, Centers for Disease Control and Prevention, declared prescription painkiller overdoses at epidemic levels. The News Release noted:

74. The death toll from overdoses of prescription painkillers has more than tripled in the past decade.

75. More than 40 people die every day from overdoses involving narcotic pain relievers like hydrocodone (Vicodin), methadone, oxycodone (OxyContin), and oxymorphone (Opana).

76. Overdoses involving prescription painkillers are at epidemic levels and now kill more Americans than heroin and cocaine combined.

77. The increased use of prescription painkillers for nonmedical reasons, along with growing sales, has contributed to a large number of overdoses and deaths. In 2010, I in every 20 people in the United States age 12 and older-a total of 12 million people-reported using prescription painkillers non-medically according to the National Survey on Drug Use and Health. Based on the data from the Drug Enforcement Administration, sales of these

[24] *See Richard C. Dart et al.*, Trends in Opioid Analgesic Abuse and Mortality in the United States, 372 N. Eng. J. Med. 241 (2015).
[25] Katherine M. Keyes *et al.*, Understanding the Rural-Urban Differences in Nonmedical Prescription Opioid Use and Abuse in the United States, 104 Am. J. Pub. Health e52 (2014).

drugs to pharmacies and health care providers have increased by more than 300 percent since 1999.

78. Prescription drug abuse is a silent epidemic that is stealing thousands of lives and tearing apart communities and families across America.

79. Almost 5,500 people start to misuse prescription painkillers every day.[26]

80. Many Americans are now addicted to prescription opioids, and the number of deaths due to prescription opioid overdose is unacceptable. In 2016, drug overdoses killed roughly 64,000 people in the United States, an increase of more than 22 percent over the 52,404 drug deaths recorded the previous year. [27]

81. Across the nation, emergency rooms are struggling with a wicked, ever- expanding epidemic of opioid addiction and abuse. Every day, more than 90 Americans lose their lives after overdosing on opioids. [28]

82. The National Institute on Drug Abuse identifies misuse and addiction to opioids epidemic. [29]

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[26] See Press Release, Ctrs. for Disease Control and Prevention, U.S. Dep't of Health and Human Servs., Prescription Painkiller Overdoses at Epidemic Levels (Nov. 1, 2011), https://www.cdc.gov/media/releases/2011/p1101_flu_pain_killer_overdose.html (accessed Jul. 12, 2018).

[27] See Ctrs. for Disease Control and Prevention, U.S. Dep't of Health and Human Servs., Provisional Counts of Drug Overdose Deaths, (August 8, 2016), https://www.cdc.gov/nchs/data/health_policy/monthly-drug-overdose-death-estimates.pdf (accessed Jul. 12, 2018)

[28] Opioid Crisis, NIH, National Institute on Drug Abuse (available at https://www.drugabuse.gov/drugs-abuse/opioids/opioid-crisis,(accessed July. 12, 2018) ("Opioid Crisis, NIH") (citing at note I Rudd RA, Seth P, David F, Scholl L, Increases in Drug and Opioid Involved Overdose Deaths - United States, 2010-2015, MMWR MORE MORTAL WKLY REP. 2016;65, doi:10.15585/mmwr.mm655051el).

[29] *See* Proclamation No. 9499, 81 Fed. Reg. 65,173 (Sept. 16, 2016) (proclaiming "Prescription Opioid and Heroin Epidemic Awareness Week").

83. In 2013, in response to a petition to require manufacturers to strengthen warnings on the labels of long-acting opioid products, the FDA warned of the "grave risks" of opioids, including "addiction, overdose, and even death." The FDA further warned, "[e]ven proper use of opioids under medical supervision can result in life-threatening respiratory depression, coma, and death." Because of those grave risks, the FDA said that long-acting or extended release opioids "should be used only when alternative treatments are inadequate."[30] The FDA required that—going forward—opioid makers of long-acting formulations clearly communicate these risks on their labels.

84. In 2016, the FDA expanded its warnings for immediate-release opioid pain medications, requiring similar changes to the labeling of immediate-release for opioid pain medications as it had for extended release opioids in 2013. The FDA also required several additional safety-labeling changes across all prescription opioid products to include additional information on the risk of these medications.[31]

85. The facts on which the FDA relied in 2013 and 2016 were well known to Defendants for many years since they began marketing these drugs.

86. The prescription opioid manufacturers and distributors, including the Defendants, have continued their wrongful, intentional, and unlawful conduct, despite their knowledge that such conduct is causing and/or continuing to the national, state, and local opioid epidemic.

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[30] Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Eval. & Res., to Andrew Kolodny, M.D., Pres. Physician for Responsible Opioid Prescribing, Re Docket No. FDA-2012-P-0818 (Sept. 10, 2013).

[31] FDA announces enhanced warnings for immediate-release opioid pain medications related to risks of misuse, abuse, addiction, overdose and death. Available at http://www.fda.gov/newsevents/newsroom/pressannouncements/ucm491739.htm (accessed July 12, 2018).

II. THE MANUFACTURER DEFENDANTS' FALSE, DECEPTIVE AND UNFAIR MARKETING OF OPIOIDS

87. The opioid epidemic did not happen by accident.

88. Before the 1990s, generally accepted standards of medical practice dictated that opioids should only be used short-term for acute pain, pain relating to recovery from surgery, or for cancer or palliative (end-of-life) care. Due to the lack of evidence that opioids improved patients' ability to overcome pain and function, coupled with evidence of greater pain complaints as patients developed tolerance to opioids over time and the serious risk of addiction and other side effects, the use of opioids for chronic pain was discouraged or prohibited. As a result, doctors generally did not prescribe opioids for chronic pain.

89. Each Manufacturer Defendant has conducted, and has continued to conduct, a marketing scheme designed to persuade doctors and patients that opioids can and should be used for chronic pain, resulting in opioid treatment for a far broader group of patients who are much more likely to become addicted and suffer other adverse effects from the long-term use of opioids. In connection with this scheme, each Manufacturer Defendant spent, and continues to spend, millions of dollars on promotional activities and materials that falsely deny or trivialize the risks of opioids while overstating the benefits of using them for chronic pain.

90. The Manufacturer Defendants have made false and misleading claims, contrary to the language on their drugs' labels, regarding the risks of using their drugs that: (1) downplayed the serious risk of addiction; (2) created and promoted the concept of "pseudo addiction" when signs of actual addiction began appearing and advocated that the signs of addiction should be treated with more opioids; (3) exaggerated the

effectiveness of screening tools to prevent addiction; (4) claimed that opioid dependence and withdrawal are easily managed; (5) denied the risks of higher opioid dosages; and (6) exaggerated the effectiveness of "abuse-deterrent" opioid formulations to prevent abuse and addiction. The Manufacturer Defendants have also falsely touted the benefits of long-term opioid use, including the supposed ability of opioids to improve function and quality of life, even though there was no scientifically reliable evidence to support the Manufacturer Defendants' claims.

91. The Manufacturer Defendants have disseminated these common messages to reverse the popular and medical understanding of opioids and risks of opioid use. They disseminated these messages directly, through their sales representatives, in speaker groups led by physicians the Manufacturer Defendants recruited for their support of their marketing messages, and through unbranded marketing and industry-funded front groups.

92. Defendants' efforts have been wildly successful. Opioids are now the most prescribed class of drugs. Globally, opioid sales generated $11 billion in revenue for drug companies in 2010 alone; sales in the United States have exceeded $8 billion in revenue annually since 2009.[32] In an open letter to the nation's physicians in August 2016, the then-U.S. Surgeon General expressly connected this "urgent health crisis" to "heavy marketing of opioids to doctors ... [m]any of [whom] were even taught - incorrectly - that opioids are not addictive when prescribed for legitimate pain.[33] This epidemic has resulted in a flood

[32] *See* Katherine Eban, Oxycontin: Purdue Pharma 's Painful Medicine, Fortune, Nov. 9, 2011. http://fortune.com/2011/11/09/oxycontin-purdue-pharmas-painful-medicine/ (accessed July 13, 2018); David Crow, Drugmakers Hooked on $l0bn Opioid Habit, Fin. Times, Aug. 10,2016, https://www.ft.com/content/f6e989a8-5dac-11e6-bb77-a121aa8abd95 (accessed July 12, 2018).
[33] Letter from Vivek H. Murthy, U.S. Surgeon General (Aug. 2016), http://time.com/4468400/surgeon-general-letter-opioid-addiction/ (accessed July 17, 2018)..

of prescription opioids available for illicit use or sale (the supply), and a population of patients physically and psychologically dependent on them (the demand). And when those patients can no longer afford or obtain opioids from licensed dispensaries, they often tum to the street to by prescription opioids or even non-prescription opioids, like heroin.

93. The Manufacturer Defendants intentionally continued their conduct, as alleged herein, with knowledge that such conduct was creating the opioid nuisance and causing the harms and damages alleged herein.

a. Each Manufacturer Defendant used multiple avenues to disseminate their false and deceptive statements about opioids.

94. The Manufacturer Defendants spread their false and deceptive statements by marketing their branded opioids directly to doctors and patients throughout the United States. Defendants also deployed seemingly unbiased and independent third parties that they controlled to spread their false and deceptive statements about the risks and benefits of opioids for the treatment of chronic pain throughout the State and Plaintiff's community.

95. Across the pharmaceutical industry, "core message" development is funded and overseen on a national basis by corporate headquarters. This comprehensive approach ensures that the Manufacturer Defendants' messages are accurately and consistently delivered across marketing channels - including detailing visits, speaker events, and advertising - and in each sales territory. The Manufacturer Defendants consider this high level of coordination and uniformity crucial to successfully marketing their drugs.

96. The Manufacturer Defendants ensure marketing consistency nationwide through national and regional sales representative training; national training of local medical liaisons, the

company employees who respond to physician inquiries; centralized speaker training; single sets of visual aids, speaker slide decks, and sales training materials; and nationally coordinated advertising. The Manufacturer Defendants' sales representatives and physician speakers were required to stick to prescribed talking points, sales messages, and slide decks, and supervisors rode along with them periodically to both check on their performance and compliance.

i. Direct Marketing

97. Defendants engaged in widespread advertising campaigns touting the benefits of their branded drugs. Defendants published print advertisements in a broad array of medical journals, ranging from those aimed at specialists, such as the *Journal of Pain* and *Clinical Journal of Pain*, to journals with wider medical audiences, such as the *Journal of the American Medical Association*. Defendants' advertising budgets peaked in 2011, when they collectively spent more than $14 million on the medical journal advertising of opioids, nearly triple what they spent in 2001. The 2011 total includes $8.3 million by Purdue, $4.9 million by Janssen, and $1.1 million by Endo.[34]

98. A number of these branded advertisements deceptively portrayed the benefits of opioid therapy for chronic pain.

    a. A 2005 Purdue advertisement for OxyContin that ran in the *Journal of Pain* touted the drug as an "around-the-clock analgesic . . . for an extended period of time." The advertisement featured a man and boy fishing and proclaimed that "There Can Be Life With Relief." This depiction falsely implied that

[34] In 2011, Actavis spent less than $100,000 on such advertising, and Cephalon spent nothing. These companies' medical journal advertising peaked earlier, with Actavis spending $11.7 million in 2005, and Cephalon spending about $2 million in each of 2007 and 2008.

OxyContin provides both effective long-term pain relief and functional improvement, claims that, as described below, are unsubstantiated and contradicted in medical literature.

b. Endo distributed and made available on its website opana.com a pamphlet promoting Opana ER with photographs depicting patients with physically demanding jobs like construction worker, chef, and teacher, misleadingly implying that the drug would provide long-term pain-relief and functional improvement. Upon information and belief, Purdue also ran a series of ads, called "Pain vignettes," for OxyContin in 2012 in medical journals. These ads featured chronic pain patients and recommended OxyContin for each. One ad described a "54-year-old writer with osteoarthritis of the hands" and implied that OxyContin would help the writer work more effectively.

99. Second, each Manufacturer Defendant promoted the use of opioids for chronic pain through "detailers" - sales representatives who visited individual doctors and medical staff in their offices - and small-group speaker programs. The Manufacturer Defendants have not corrected this misinformation. Instead, each Defendant devoted massive resources to direct sales contacts with doctors. Upon information and belief, in 2014 alone, the Manufacturer Defendants spent in excess of $168 million on detailing branded opioids to doctors, more than twice what they spent on detailing in 2000.

100. Defendants developed sophisticated plans to select prescribers for sales visits based on their specialties and prescribing habits. In accordance with common industry practice, Defendants purchase and closely analyze prescription sales data from IMS Health. This data allows them to precisely track the rates of initial prescribing and

renewal by individual doctors, which in turn allows them to target, tailor, and monitor the impact of their appeals.

101. Defendants, in particular, relied upon "influence mapping," *i.e.*, using decile rankings or similar breakdowns to identify the high-volume prescribers on whom detailing would have the greatest sales impact. Endo, for example, identified prescribers representing 30% of its nationwide sales volume and planned to visit these physicians three times per month. Defendants also closely monitored doctors' prescribing after a sales representative's visit to allow them to refine their planning and messaging and to evaluate and compensate their detailers.

102. In addition to making sales calls, Defendants' detailers also identified doctors to serve, for payment, on Defendants' speakers' bureaus and to attend programs with speakers and meals paid for by Defendants. Defendants almost always selected physicians who were "product loyalists," as they were sure to be asked whether they prescribe the drug themselves. Endo, for instance, sought to use specialists in pain medicine—including high prescribers of its drugs—as local "thought leaders" to market Opana ER to primary care doctors. Such invitations are lucrative to the physicians selected for these bureaus; honorarium rates range from $800 to $2,000 per program, depending on the type of event, speaker training is typically compensated at $500 per hour.

103. These speaker programs and associated speaker trainings serve three purposes:

a. they provide an incentive to doctors to prescribe, or increase their prescriptions of, a particular drug;

b. a forum in which to further market to the speaker him or herself; and

c. an opportunity to market to the speaker's peers.

104. Defendants grade their speakers and future opportunities are based on speaking performance, post-program sales, and product usage. Defendants also track the prescribing of event attendees, with Endo noting that "physicians who came into our speaker programs wrote more prescriptions for Opana ER after attending than before." It would make little sense for Defendants to devote significant resources to programs that did not increase their sales.

105. Defendants devoted massive resources to these direct sales contacts with prescribers. In 2014, Defendants collectively spent $168 million on detailing branded opioids to physicians nationwide. This figure includes $108 million spent by Purdue, $34 million by Janssen, $13 million by Cephalon, $10 million by Endo, and $2 million by Actavis. The total figure is more than double Defendants' collective spending on detailing in 2000. Detailers' role in Defendants' overall promotional efforts was also carefully calibrated; Endo, for example, found that devoting 61% of its marketing budget to sales representatives reflected an "[a]ppropriate combination of personal . . . and non-personal . . . selling initiatives."

ii. Indirect marketing

106. Drug companies that make, market, and distribute opioids are subject to generally applicable rules requiring truthful marketing of prescription drugs. A drug company's branded marketing, which identifies and promotes a specific drug, must: (a) be consistent with its label and supported by substantial scientific evidence; (b) not include false or misleading statements or material omissions; and (c) fairly balance

the drug's benefits and risks.[35] The regulatory framework governing the marketing of specific drugs reflects a public policy designed to ensure that drug companies, which are best suited to understand the properties and effects of their drugs, are responsible for providing prescribers with the information they need to accurately assess the risks and benefits of drugs for their patients.

107. Further, the Federal Food, Drug, and Cosmetic Act ("FDCA") prohibits the sale in interstate commerce of drugs that are "misbranded." A drug is "misbranded" if it lacks "adequate directions for use" or if the label is false or misleading "in any particular."[36] "Adequate directions for use" are directions "under which the layman can use a drug safely and for the purposes for which it is intended."[37] "Labeling" includes more than the drug's physical label; it also includes "all . . . other written, printed, or graphic matter . . . accompanying" the drug, including promotional material.[38] "The term "accompanying" is interpreted broadly to include promotional materials—posters, websites, brochures, books, and the like—disseminated by or on behalf of the manufacturer of the drug.[39] Thus, Defendants' promotional materials are part of their drugs' labels and are required to be accurate, balanced, and not misleading.

108. Labeling is misleading if it is not based on substantial evidence, if it materially misrepresents the benefits of the drug, or if it omits material information about or minimizes the frequency or severity of a product's risks. "The most serious risks set forth in a product's labeling are generally material to any

[35] 21 U.S.C. § 352(a); 21 C.F.R. §§ 1.21(a), 202.1(e)(3), 202.1(e)(6).
[36] 21 U.S.C. §§ 352.
[37] 21 C.F.R. § 201.5.
[38] 21 U.S.C. § 321(m).
[39] See *id*.

presentation of efficacy." The FDA notes that "[b]ecause people expect to see risk information, there is no reason for them to imagine that the product has important risks that have been omitted . . . especially if some risks are included."[40] Promotion that fails to present the most important risks of the drug as prominently as its benefits lacks fair balance and is therefore deceptive.

109. It is also illegal for drug companies to distribute materials that exclude contrary evidence or information about the drug's safety or efficacy or present conclusions that "clearly cannot be supported by the results of the study."[41] Further, drug companies must not make comparisons between their drugs and other drugs that represent or suggest that "a drug is safer or more effective than another drug in some particular when it has not been demonstrated to be safer or more effective in such particular by substantial evidence or substantial clinical experience."[42]

110. While the FDA must approve a drug's label, it is the drug company's responsibility to ensure that the material in its label is accurate and complete and is updated to reflect any new information.[43] Promotional materials also must be submitted to the FDA when they are first used or disseminated. The FDA does not have to approve these materials in advance; if, upon review, the FDA determines that materials marketing a drug are misleading, it can issue an untitled letter or warning letter. The FDA

[40] FDA, Draft Guidance for Industry, Presenting Risk Information in Prescription Drug and Medical Device Promotion, May 2009, at 14.
[41] 21 C.F.R. § 99.101(a)(4).
[42] 21 C.F.R. § 202.1(e)(6)(ii).
[43] See 21 C.F.R. § 201.56 (providing general requirements for prescription drug labeling); see also *Wyeth v. Levine*, 555 U.S. 555 (2009) (holding that a drug company bears responsibility for the content of its drug labels at all times); 21 C.F.R. § 314.70(c)(6) (iii)(A-C) (allowing manufacturers to make changes that "strengthen . . . a warning, precaution, or adverse reaction" or "strengthen a statement about drug abuse, dependence, psychological effect, or overdosage").

uses untitled letters for violations such as overstating the effectiveness of the drug or making claims without context or balanced information. Warning letters address promotions involving safety or health risks and indicate the FDA may take further enforcement action.

111. The Manufacturer Defendants' indirectly marketed their opioids using unbranded advertising, paid speakers and "key opinion leaders" ("KOLs"), influenced guidelines and industry-funded organizations posing as neutral and credible professional societies and patient advocacy groups (referred to hereinafter as "Front Groups").

112. Even where such unbranded messages were channeled through third-party vehicles, Defendants adopted these messages as their own when they cited to, edited, approved, and distributed such materials knowing they were false, misleading, unsubstantiated, unbalanced, and incomplete. Unbranded brochures and other materials that are "disseminated by or on behalf of [the] manufacturer" constitute drug "labeling" that may not be false or misleading in any particular. *See* 21 C.F.R. §202.1(e)(7)(l)(2).[44] Defendants' sales representatives distributed third-party marketing material that was deceptive to Defendants' target audiences. Defendants are responsible for these materials.

I. CMEs

[44] This regulation provides: "Brochures, booklets, mailing pieces, detailing pieces, file cards, bulletins, calendars, price lists, catalogs, house organs, letters, motion picture films, film strips, lantern slides, sound recordings, exhibits, literature, and reprints and similar pieces of printed, audio, or visual matter descriptive of a drug and the references published . . . containing drug information supplied by the manufacturer, packer, or distributor of the drug and which are disseminated by or on behalf of its manufacturer, packer, or distributor are hereby determined to be labeling, as defined in section 201(m) of the act." As labeling, such third party-created content distributed by a drug company may not be misleading and must meet the accuracy, substantiation, and fair balance requirements in the FDCA.

113. CMEs are ongoing professional education programs provided to doctors. Doctors are required to attend a certain number and, often, type of CME programs each year as a condition of their licensure. These programs are delivered in person, often in connection with professional organizations' conferences, online, or through written publications. Doctors rely on CMEs not only to satisfy licensing requirements, but to get information on new developments in medicine or to deepen their knowledge in specific areas of practice. Because CMEs are typically delivered by KOLs who are highly respected in their fields, and are thought to reflect these physicians' medical expertise, they can be especially influential with doctors.

114. The countless doctors and other health care professionals who participate in accredited CMEs constitute an enormously important audience for opioid reeducation. As one target, Defendants aimed to reach general practitioners, whose broad area of focus and lack of specialized training in pain management made them particularly dependent upon CMEs and, as a result, especially susceptible to Defendants' deceptions.

115. In all, Defendants sponsored CMEs that were delivered thousands of times, promoting chronic opioid therapy and supporting and disseminating the deceptive and biased messages described in this Complaint. These CMEs, while often generically titled to relate to the treatment of chronic pain, focused on opioids to the exclusion of alternative treatments, inflated the benefits of opioids, and frequently omitted or downplayed their risks and adverse effects.

116. The American Medical Association ("AMA") has recognized that support from drug companies with a financial interest in the content being promoted "creates

conditions in which external interests could influence the availability and/or content" of the programs and urges that "[w]hen possible, CME[s] should be provided without such support or the participation of individuals who have financial interests in the educational subject matter."[45]

117. Dozens of CMEs that were available to and attended or reviewed by doctors during the relevant time period did not live up to the AMA's standards.

118. The influence of Defendants' funding on the content of these CMEs is clear. One study by a Georgetown University Medical Center professor compared the messages retained by medical students who reviewed an industry-funded CME article on opioids versus another group who reviewed a non-industry-funded CME article. The industry-funded CME did not mention opioid-related death once; the non-industry-funded CME mentioned opioid-related death 26 times. Students who read the industry-funded article more frequently noted the impression that opioids were underused in treating chronic pain. The "take-aways" of those reading the non-industry-funded CME mentioned the risks of death and addiction much more frequently than the other group. Neither group could accurately identify whether the article they read was industry-funded, making clear the difficulty health care providers have in screening and accounting for source bias.[46]

[45] Opinion 9.0115, Financial Relationships with Industry in CME, Am. Med. Ass'n (Nov. 2011), available at https://www.ama-assn.org/delivering-care/financial-relationships-industry-continuing-medical-education (accessed July 13, 2018).

[46] Adriane Fugh-Berman, Marketing Messages in Industry-Funded CME, PharmedOut (June 25, 2010), available at www.pharmedout.org/pdf/Conf2010/Fugh-BermanPrescriptionforConflict6-25-10.pdf (accessed July 13, 2018).

119. By sponsoring CME programs presented by Front Groups like APF, AAPM, and others, Defendants could expect messages to be favorable to them, as these organizations were otherwise dependent on Defendants for other projects. The sponsoring organizations honored this principle by hiring pro-opioid KOLs to give talks that supported chronic opioid therapy. Defendant-driven content in these CMEs had a direct and immediate effect on prescribers' views on opioids. Producers of CMEs and Defendants measured the effects of CMEs on prescribers' views on opioids and their absorption of specific messages, confirming the strategic marketing purpose in supporting them.

120. For example, Purdue sponsored a 2011 CME taught by KOL Lynn Webster via webinar titled *Managing Patient's Opioid Use: Balancing the Need and Risk*. This presentation also deceptively instructed prescribers that screening tools, patient agreements, and urine test prevented "overuse of prescriptions" and "overdose deaths." At the time, Dr. Webster was receiving significant funding from Purdue. Versions of Dr. Webster's Opioid Risk Tool appear on, or are linked to, websites run by Purdue (and other Defendants). The webinar was available to and was intended to reach Charleston County prescribers.

121. Purdue also sponsored a CME program entitled *Path of the Patient, Managing Chronic Pain in Younger Adults at Risk for Abuse*. *Path of the Patient* was devoted entirely to the message of treating chronic pain with opioids. Although the program purported to instruct a treating physician how to manage chronic pain in younger adults at risk for abuse, it does no such thing.

122. This "educational" program, addressing treatment of a population known to be particularly susceptible to opioid addiction, presents none of the alternative treatment options available, only discussing treatment of chronic pain with opioids.

123. In a role-play in *Path of the Patient*, a patient who suffers from back pain tells his doctor that he is taking twice as many hydrocodone pills as directed. The doctor reports that the pharmacy called him because of the patient's early refills. The patient has a history of drug and alcohol abuse. Despite these facts, the narrator notes that, because of a condition known as "pseudoaddiction," the doctor should not assume his patient is addicted even if he persistently asks for a specific drug, seems desperate, hoards medicine, or "overindulges in unapproved escalating doses." The doctor in the role- play treats this patient by prescribing a high-dose, long-acting opioid. This CME was available online and was intended to reach County prescribers.

124. Purdue also sponsored a CME titled *Overview of Management Options* issued by the American Medical Association in 2003, 2007, and 2013 (the latter of which is still available for CME credit). The CME was edited by KOL Russel Portenoy, among others. It deceptively instructs physicians that NSAIDs and other drugs, but not opioids, are unsafe at high doses. In reality, the data indicates that patients on high doses of opioids are more likely to experience adverse outcomes than patients on lower doses of the drugs. Dr. Portenoy received research support, consulting fees, and honoraria from Purdue (among others), and was a paid Purdue consultant. This CME was presented online in the United States and was available to Charleston County prescribers.

II. Unbranded Advertisement

125. The Manufacturer Defendants marketed through third-party, unbranded advertising to avoid regulatory scrutiny because that advertising is not submitted to

and typically is not reviewed by the FDA. The Manufacturer Defendants also used third-party, unbranded advertising to give the false appearance that the deceptive messages came from an independent and objective source. Like the tobacco companies, the Manufacturer Defendants used third parties that they funded, directed, and controlled to carry out and conceal their scheme to deceive doctors and patients about the risks and benefits of long term opioid use for chronic pain. .

126. Rather than find a way to actually test the safety and efficacy of opioids for long- term use, Defendants led people to believe that they already had. Defendants created a body of false, misleading, and unsupported medical and popular literature about opioids that (a) understated the risks and overstated the benefits of long-term use; (b) appeared to be the result of independent, objective research; and (c) was thus more likely to shape the perceptions of prescribers, patients and payors. This literature was, in fact, marketing material focused on persuading doctors and consumers that the benefits of long-term opioid use outweighed the risks.

127. To accomplish this, Defendants—sometimes through third-party consultants and/or advocacy organizations—commissioned, edited, and arranged for the placement of favorable articles in academic journals. Defendants' internal documents reveal plans to submit research papers and "studies" to long lists of journals, including back-up options and last resort, "fast-track" application journals, which they could use if the pending paper was rejected everywhere else.

128. Defendants coordinated the timing and publication of manuscripts, abstracts, posters/oral presentations, and educational materials in peer-reviewed journals and other publications to support the launch and sales of their drugs. The plans

for these materials did not originate in the departments within the Defendant organizations that were responsible for research, development or any other area that would have specialized knowledge about the drugs and their effects on patients, but in Defendants' marketing departments and with Defendants' marketing and public relations consultants. Defendants often relied on "data on file" or presented posters, neither of which are subject to peer review. They also published their articles not through a competitive process, but in paid journal supplements, which allowed Defendants to publish, in nationally circulated journals, studies supportive of their drugs.

129. Defendants also made sure that favorable articles were disseminated and cited widely in the medical literature, even where references distorted the significance or meaning of the underlying study. Most notably, Purdue promoted a 1980 reference in the well-respected *New England Journal of Medicine*: J. Porter & H. Jick, *Addiction Rare in Patients Treated with Narcotics*, 302(2) *New Eng. J. Med.* 123 (1980) ("Porter-Jick Letter"). It is cited more than a thousand times in Google Scholar. It also appears as a reference in two CME programs in 2012 sponsored by Purdue and Endo.[47] Defendants and those acting on their behalf fail to reveal that this "article" is actually a letter-to-the-editor, not a peer-reviewed study (or any kind of study at all). The Porter-Jick Letter, reproduced in full below, describes a review of the charts of hospitalized patients who had received opioids. (Because it was a 1980 study,

[47] AAPM, Safe Opioid Prescribing Course, February 25-26, 2012, sponsored by Purdue and Endo; "Chronic Pain Management and Opioid Use," October 11, 2012, sponsored by Purdue. CMEs are available for online credit.

standards of care almost certainly would have limited opioids to acute or end-of-life situations, not chronic pain.)

130. The Porter-Jick Letter notes that, when these patients' records were reviewed, it found almost no references to signs of addiction, though there is no indication that caregivers were instructed to assess or document signs of addiction. None of these serious limitations is disclosed when Defendants, or those acting on their behalf, cite the Porter-Jick Letter, typically as the sole scientific support for the proposition that opioids are rarely addictive, even when taken long-term. In fact, Dr. Jick later complained that his letter had been distorted and misused.

131. By way of another example, until at least February 2009, Mallinckrodt provided an educational grant to Pain-Topics.org, a now-defunct website that touted itself as a noncommercial resource for healthcare professionals, providing open access to clinical news, information, research, and education for a better understanding of evidence-based pain-management practices.

132. Among other content, the website included a handout titled "Oxycodone Safety Handout for Patients," which advised practitioners that: "Patients' fears of opioid addiction should be dispelled."[48] The handout included several false and misleading statements concerning the risk of addiction associated with prescription opioids:

> Will you become dependent on or addicted to oxycodone?
>
> - After a while, oxycodone causes physical dependence. That is, if you suddenly stop the medication you may experience uncomfortable withdrawal symptoms, such as diarrhea, body aches,

[48] Lee A. Kral & Stewart B. Leavitt, Oxycodone Safety Handout for Patients, Pain-Topics.Org (June 2007), http://paincommunity.org/blog/wp-content/uploads/OxycodoneHandout.pdf

weakness, restlessness, anxiety, loss of appetite, and other ill feelings. These may take several days to develop.

- This is not the same as addiction, a disease involving a craving for the drug, loss of control over taking it or compulsive use, and using it despite harm. Addiction to oxycodone in persons without a recent history of alcohol or drug problems is rare.[49]

133. Additionally, upon information and belief, the FAQ section of Pain-Topics.org contained false and misleading information downplaying the dangers of prescription opioid use including support for the term "pseudoaddiction."

134. Another document believed to be formerly available on the website, "Commonsense Oxycodone Prescribing & Safety," falsely suggests that generic oxycodone is less prone to abuse and diversion than branded oxycodone: "Anecdotally, it has been observed that generic versions of popularly abused opioids usually are less appealing; persons buying drugs for illicit purposes prefer brand names because they are more recognizable and the generics have a lower value 'on the street,' which also makes them less alluring for drug dealers."[50]

135. Defendants worked not only to create or elevate favorable studies in the literature, but to discredit or bury negative information. Defendants' studies and articles often targeted articles that contradicted Defendants' claims or raised concerns about chronic opioid therapy. In order to do so, Defendants—often with the help of third-party consultants—targeted a broad range of media to get their message out, including negative review articles, letters to the editor, commentaries, case-study reports, and newsletters.

[49] *Id.*
[50] Lee A. Kral, Commonsense Oxycodone Prescribing & Safety, Pain-Topics.org (June 2007), https://pdfs.semanticscholar.org/6bb9/f09b4bf2c9cc7b4eb9917985b301a6b0edce.pdf.

136. Defendants' strategies—first, to plant and promote supportive literature and then, to cite the pro-opioid evidence in their promotional materials, while failing to disclose evidence that contradicts those claims—are in dereliction of their legal obligations. The strategies were intended to, and did, knowingly and intentionally distort the truth regarding the risks, benefits and superiority of opioids for chronic pain relief resulting in distorted prescribing patterns.

III. KOLs

137. Defendants cultivated a small circle of doctors who, upon information and belief, were selected and sponsored by Defendants solely because they favored the aggressive treatment of chronic pain with opioids. Defendants' support helped these doctors become respected industry experts. In return, these doctors repaid Defendants by touting the benefits of opioids to treat chronic pain.

138. Pro-opioid doctors have been at the hub of Defendants' promotional efforts, presenting the appearance of unbiased and reliable medical research supporting the broad use of opioid therapy for chronic pain. KOLs have written, consulted on, edited, and lent their names to books and articles, and given speeches and CMEs supportive of chronic opioid therapy. They have served on committees that developed treatment guidelines that strongly encourage the use of opioids to treat chronic pain (even while acknowledging the lack of evidence in support of that position) and on the boards of pro-opioid advocacy groups and professional societies that develop, select, and present CMEs. Defendants were able to exert control of each of these modalities through their KOLs.

139. In return, the KOLs' association with Defendants provided not only money, but prestige, recognition, research funding, and avenues to publish. This positioned them to exert even more influence in the medical community.

140. Although some KOLs initially may have advocated for more permissive opioid prescribing with honest intentions, Defendants cultivated and promoted only those KOLs who could be relied on to help broaden the chronic opioid therapy market. Defendants selected, funded, and elevated those doctors whose public positions were unequivocal and supportive of using opioids to treat chronic pain.[51] These doctors' professional reputations were then dependent on continuing to promote a pro-opioid message, even in activities that were not directly funded by the drug companies.

141. Defendants cited and promoted favorable studies or articles by these KOLs. By contrast, Defendants did not support, acknowledge, or disseminate the publications of doctors critical of the use of chronic opioid therapy. Indeed, one prominent KOL sponsored by Defendants, Russell Portenoy, stated that he was told by a drug company that research critical of opioids (and the doctors who published that research) would never obtain funding. Some KOLs have even gone on to become direct employees and executives of Defendants, like Dr. David Haddox, Purdue's Vice President of Risk Management, or Dr. Bradley Galer, Endo's former Chief Medical Officer.

142. Defendants provided substantial opportunities for KOLs to participate in research studies on topics Defendants suggested or chose, with the predictable effect of ensuring that many favorable studies appeared in the academic literature. As

[51] Opioid-makers were not the first to mask their deceptive marketing efforts in purported science. The tobacco industry also used KOLs in its effort to persuade the public and regulators that tobacco was not addictive or dangerous. For example, the tobacco companies funded a research program at Harvard and chose as its chief researcher a doctor who had expressed views in line with industry's views. He was dropped when he criticized low-tar cigarettes as potentially more dangerous, and later described himself as a pawn in the industry's campaign.

described by Dr. Portenoy, drug companies would approach him with a study that was well underway and ask if he would serve as the study's author. Dr. Portenoy regularly agreed.

143. Defendants also paid KOLs to serve as consultants or on their advisory boards and give talks or present CMEs, typically over meals or at conferences. Since 2000, Cephalon, for instance, has paid doctors more than $4.5 million for programs relating to its opioids.

144. These KOLs were carefully vetted to ensure that they were likely to remain on-message and supportive of a pharmaceutical industry agenda. One measure was a doctor's prior work for trusted Front Groups.

145. Defendants kept close tabs on the content of the misleading materials published by these KOLs. In many instances, they also scripted what these KOLs said—as they did with all their recruited speakers. The KOLs knew, or deliberately ignored, the misleading way in which they portrayed the use of opioids to treat chronic pain to patients and prescribers, but they continued to publish those misstatements to benefit themselves and Defendants, all the while causing harm to County prescribers and patients.

IV. TREATMENT GUIDELINES

146. Treatment guidelines have been particularly important in securing acceptance for chronic opioid therapy. They are relied upon by doctors, especially the general practitioners and family doctors targeted by Defendants, who are otherwise not experts, nor trained, in the treatment of chronic pain. Treatment guidelines not only directly inform doctors' prescribing practices, but are cited throughout the scientific literature and referenced by third-party payors in determining whether they should cover treatments for specific indications. Furthermore, Endo's internal documents indicate that

pharmaceutical sales representatives employed by Endo, Actavis, and Purdue discussed treatment guidelines with doctors during individual sales visits.

i. FSMB

147. The Federation of State Medical Boards ("FSMB") is a trade organization representing the various state medical boards in the United States. The state boards that comprise the FSMB membership have the power to license doctors, investigate complaints, and discipline physicians. The FSMB finances opioid- and pain-specific programs through grants from Defendants.

148. In 1998, the FSMB developed *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain* ("FSMB Guidelines"), which FSMB admitted was produced "in collaboration with pharmaceutical companies."[52] The FSMB Guidelines taught not that opioids could be appropriate in limited cases or after other treatments had failed, but that opioids were "essential" for treatment of chronic pain, including as a first prescription option. The FSMB Guidelines failed to mention risks relating to respiratory depression and overdose, and they discussed addiction only in the sense that "inadequate understandings" of addiction can lead to "inadequate pain control."

149. A 2004 iteration of the FSMB Guidelines and the 2007 book adapted from the 2004 guidelines, *Responsible Opioid Prescribing*, also make these same claims. These

[52] FSMB, "Position of the FSMB in Support of Adoption of Pain Management Guidelines" (2000), http://www.painpolicy.wisc.edu/sites/default/files/sites/www.painpolicy.wisc.edu/files/FSMPwp.pdf

guidelines were posted online and were available to and intended to reach County physicians.

150. The publication of *Responsible Opioid Prescribing* was backed largely by drug manufacturers, including Cephalon, Endo, and Purdue. The FSMB financed the distribution of *Responsible Opioid Prescribing* by its member boards by contracting with drug companies, including Endo and Cephalon, for bulk sales and distribution to sales representatives (for distribution to prescribing doctors).

151. In all, 163,131 copies of *Responsible Opioid Prescribing* were distributed to state medical boards (and through the boards, to practicing doctors), and the FSMB benefitted by earning approximately $250,000 in revenue and commissions from their sale. The FSMB website describes the book as the "leading continuing medication education (CME) activity for prescribers of opioid medications."

152. Drug companies relied on FSMB guidelines to convey the message that "under-treatment of pain" would result in official discipline, but no discipline would result if opioids were prescribed as part of an ongoing patient relationship and prescription decisions were documented. FSMB turned doctors' fear of discipline on its head—doctors, who used to believe that they would be disciplined if their patients became addicted to opioids, were taught that they would be punished instead if they failed to prescribe opioids to their patients with pain.

153. FSMB, more recently, has moderated its stance. Although the 2012 revision of *Responsible Opioid Prescribing* continued to teach that "pseudoaddiction" is real and that opioid addiction risk can be managed through risk screening, it no longer recommended

chronic opioid therapy as a first choice after the failure of over-the-counter medication and has heightened its addiction and risk warnings.

ii. *AAPM/APS Guidelines*

154. AAPM and the APS are professional medical societies, each of which received substantial funding from Defendants from 2009 to 2013 (with AAPM receiving over $2 million).

155. They issued a consensus statement in 1997, *The Use of Opioids for the Treatment of Chronic Pain*, which endorsed opioids to treat chronic pain and claimed that the risk that patients would become addicted to opioids was low.[53] The co-author of the statement, Dr. Haddox, was, at the time, a paid speaker for Purdue. Dr. Portenoy was the sole consultant. The consensus statement, which also formed the foundation of the FSMB Guidelines, remained on AAPM's website until 2011. The statement was taken down from AAPM's website only after a doctor complained, though it lingers on the internet elsewhere.[54]

156. AAPM and APS issued their own guidelines in 2009 ("AAPM/APS Guidelines" or "Consensus Recommendation") and continued to recommend the use of opioids to treat chronic pain.[55] Fourteen of the 21 panel members who drafted the AAPM/APS Guidelines, including KOLs Dr. Portenoy and Dr. Perry Fine of the University of Utah, received support from Janssen, Cephalon, Endo, and Purdue.

[53] Consensus statement, The Use of Opioids for the Treatment of Chronic Pain, APS & AAPM (1997), available at https://www.jpain.org/article/S1082-3174(97)80022-0/pdf

[54] Id.

[55] Roger Chou et al., Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain, 10(2) The Journal of Pain: Official Journal of the American Pain Society 113-130 (2009)

157. The 2009 Guidelines promote opioids as "safe and effective" for treating chronic pain, despite acknowledging limited evidence, and conclude that the risk of addiction is manageable for patients regardless of past abuse histories. One panel member, Dr. Joel Saper, Clinical Professor of Neurology at Michigan State University and founder of the Michigan Headache & Neurological Institute, resigned from the panel because of his concerns that the 2009 Guidelines were influenced by contributions that drug companies, including Defendants, made to the sponsoring organizations and committee members. These AAPM/APS Guidelines have been a particularly effective channel of deception and have influenced not only treating physicians, but also the body of scientific evidence on opioids; the Guidelines have been cited 732 times in academic literature, were disseminated in Palm Beach County during the relevant time period, are still available online, and were reprinted in the *Journal of Pain*.

158. Defendants widely referenced and promoted the 2009 Guidelines without disclosing the acknowledged lack of evidence to support them.

iii. *American Geriatrics Society*

159. The American Geriatrics Society ("AGS"), a nonprofit organization serving health care professionals who work with the elderly, disseminated guidelines regarding the use of opioids for chronic pain in 2002 (*The Management of Persistent Pain in Older Persons*, hereinafter "2002 AGS Guidelines") and 2009 (*Pharmacological Management of Persistent Pain in Older Persons*, hereinafter "2009 AGS Guidelines"). The 2009 AGS Guidelines included the following recommendations: "All patients with moderate to severe pain . . . should be considered for opioid therapy (low quality of

evidence, strong recommendation)," and "the risks [of addiction] are exceedingly low in older patients with no current or past history of substance abuse."[56] These recommendations, which continue to appear on AGS's website, are not supported by any study or other reliable scientific evidence. Nevertheless, they have been cited 278 times in Google Scholar since their 2009 publication.

160. AGS contracted with Defendants Endo, Purdue, and Janssen to disseminate the 2009 Guidelines, and to sponsor CMEs based on them. These Defendants were aware of the content of the 2009 Guidelines when they agreed to provide funding for these projects. The 2009 Guidelines were first published online on July 2, 2009. AGS submitted grant requests to Defendants including Endo and Purdue beginning July 15, 2009. Internal AGS discussions in August 2009 reveal that it did not want to receive up-front funding from drug companies, which would suggest drug company influence, but would instead accept commercial support to disseminate the publication. However, by drafting the guidelines knowing that pharmaceutical company funding would be needed, and allowing these companies to determine whether to provide support only after they had approved the message, AGS ceded significant control to these companies. Endo, Janssen, and Purdue all agreed to provide support to distribute the guidelines.

161. According to one news report, AGS has received $344,000 in funding from opioid makers since 2009.[57] Five of 10 of the experts on the guidelines panel

[56] Pharmacological Management of Persistent Pain in Older Persons, 57 J. Am. Geriatrics Soc'y 1331,
1339, 1342 (2009), available at https://onlinelibrary.wiley.com/doi/abs/10.1111/j.1532-5415.2009.02376.x (accessed July 13, 2018).

[57] John Fauber & Ellen Gabler, Narcotic Painkiller Use Booming Among Elderly, Milwaukee J. Sentinel, May 30, 2012.

disclosed financial ties to Defendants, including serving as paid speakers and consultants, presenting CMEs sponsored by Defendants, receiving grants from Defendants, and investing in Defendants' stock. The Institute of Medicine recommends that, to ensure an unbiased result, fewer than 50% of the members of a guidelines committee should have financial relationships with drug companies.

iv. *Guidelines That Did Not Receive Defendants' Support*

162. The extent of Defendants' influence on treatment guidelines is demonstrated by the fact that independent guidelines—the authors of which did not accept drug company funding—reached very different conclusions. The 2012 *Guidelines for Responsible Opioid Prescribing in Chronic Non-Cancer Pain*, issued by the American Society of Interventional Pain Physicians ("ASIPP"), warned that "[t]he recent revelation that the pharmaceutical industry was involved in the development of opioid guidelines as well as the bias observed in the development of many of these guidelines illustrate that the model guidelines are not a model for curtailing controlled substance abuse and may, in fact, be facilitating it." ASIPP's Guidelines further advise that "therapeutic opioid use, specifically in high doses over long periods of time in chronic non-cancer pain starting with acute pain, not only lacks scientific evidence, but is in fact associated with serious health risks including multiple fatalities, and is based on emotional and political propaganda under the guise of improving the treatment of chronic pain." ASIPP recommends long- acting opioids in high doses only "in specific circumstances with severe intractable pain" and only when coupled with "continuous adherence monitoring, in well- selected populations, in conjunction with or after failure of other modalities of

treatments with improvement in physical and functional status and minimal adverse effects."[58]

163. Similarly, the 2011 *Guidelines for the Chronic Use of Opioids*, issued by the American College of Occupational and Environmental Medicine, recommend against the "routine use of opioids in the management of patients with chronic pain," finding "at least moderate evidence that harms and costs exceed benefits based on limited evidence," while conceding there may be patients for whom opioid therapy is appropriate.[59]

164. The *Clinical Guidelines on Management of Opioid Therapy for Chronic Pain*, issued by the U.S. Department of Veterans Affairs ("VA") and Department of Defense ("DOD") in 2010, notes that their review:

> revealed the lack of solid evidence based research on the efficacy of long-term opioid therapy. Almost all of the randomized trials of opioids for chronic non-cancer pain were short-term efficacy studies. Critical research gaps . . . include: lack of effectiveness studies on long-term benefits and harms of opioids . . .; insufficient evidence to draw strong conclusions about optimal approaches to risk stratification . . .; lack of evidence on the utility of informed consent and opioid management plans . . .; and treatment of patients with chronic non-cancer pain at higher risk for drug abuse or misuse.[60]

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[58] Laxmaiah Manchikanti, et al., American Society of Interventional Pain Physicians (ASIPP) Guidelines for Responsible Opioid Prescribing in Chronic Non-Cancer Pain: Part 1, Evidence Assessment, 15 Pain Physician (Special Issue) S1-S66; Part 2—Guidance, 15 Pain Physician (Special Issue) S67-S116 (2012).

[59] American College of Occupational and Environmental Medicine's Guidelines for the Chronic Use of Opioids, (2011), available at: https://www.nhms.org/sites/default/files/Pdfs/ACOEM%202011-Chronic%20Pain%20Opioid%20.pdf (accessed July 13, 2018).

[60] Management of Opioid Therapy for Chronic Pain Working Group, VA/DoD Clinical Practice Guideline for Management of Opioid Therapy for Chronic Pain (May 2010), available at

V. FRONT GROUPS

165. As noted above, Defendants Cephalon, Endo, Janssen, and Purdue entered into arrangements with numerous organizations to promote opioids. These organizations depend upon Defendants for significant funding and, in some cases, for their survival. They were involved not only in generating materials and programs for doctors and patients that supported chronic opioid therapy, but also in assisting Defendants' marketing in other ways—for example, responding to negative articles and advocating against regulatory changes that would constrain opioid prescribing. They developed and disseminated pro-opioid treatment guidelines; conducted outreach to groups targeted by Defendants, such as veterans and the elderly; and developed and sponsored CMEs that focused exclusively on use of opioids to treat chronic pain. Defendants funded these Front Groups in order to ensure supportive messages from these seemingly neutral and credible third parties, and their funding did, in fact, ensure such supportive messages.

166. Several representative examples of such Front Groups are highlighted below, but there are others, too, such as APS, AGS, FSMB, American Chronic Pain Association ("ACPA"), AAPM, American Society of Pain Educators ("ASPE"), NPF, and PPSG.

167. The most prominent of Defendants' Front Groups was APF, which received more than $10 million in funding from opioid manufacturers from 2007 until it closed its doors in May 2012. Endo alone provided more than half of that funding; Purdue was next, at $1.7 million. Purdue informed APF that the grant money reflected

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https://www.va.gov/painmanagement/docs/cpg_opioidtherapy_summary.pdf (accessed July 13, 2018).

Purdue's effort to "strategically align its investments in nonprofit organizations that share [its] business interests," making clear that Purdue's funding depended upon APF continuing to support Purdue's business interests. Indeed, Purdue personnel participated in a March 2011 call with APF's "Corporate Roundtable," where they suggested that APF "[s]end ambassadors to talk about pain within companies and hospitals." Thus, Purdue suggested what role APF could play that would complement its own marketing efforts. On that call, Purdue personnel also committed to provide APF with a list of "industry state advocates" who could help promote chronic opioid therapy, individuals and groups that, upon information and belief, APF reached out to. Purdue personnel remained in constant contact with their counterparts at APF.

168. This alignment of interests was expressed most forcefully in the fact that Purdue hired APF to provide consulting services on its marketing initiatives. Purdue and APF entered into a "Master Consulting Services" Agreement on September 14, 2011. That agreement gave Purdue substantial rights to control APF's work related to a specific promotional project. Moreover, based on the assignment of particular Purdue "contacts" for each project and APF's periodic reporting on their progress, the agreement enabled Purdue to be regularly aware of the misrepresentations APF was disseminating regarding the use of opioids to treat chronic pain in connection with that project. The agreement gave Purdue—but not APF—the right to end the project (and, thus, APF's funding) for any reason. This agreement demonstrates APF's lack of independence and its willingness to surrender

to Purdue's control and commercial interests, which would have carried across all of APF's work.

169. Purdue used this agreement to conduct work with APF on the *Partners Against Pain* website. *Partners Against Pain* is a Purdue-branded site, and Purdue holds the copyright.

170. However, its ability to deploy APF on this project illustrates the degree of control Purdue exercised over APF. In 2011, it hired an APF employee to consult on the *Partners Against Pain* rollout, to orchestrate the media campaign associated with the launch of certain content on the website, and to make public appearances promoting the website along with a celebrity spokesperson. Purdue contemplated paying this consultant $7,500 in fees and expenses for 26 hours of work. Purdue would require this consultant to "to discuss and rehearse the delivery of [Purdue's] campaign messages" and Purdue committed that "[m]essage points will be provided to [the] Consultant in advance and discussed on [a planned] call." At all times, decisions regarding the final content on the *Partners Against Pain* website were "at the sole discretion of Purdue."

171. APF also volunteered to supply one of its staff (a medical doctor or a nurse practitioner) to assist Purdue as a consultant and spokesperson for the launch of one of Purdue's opioid-related projects, *Understanding & Coping with Lower Back Pain*, which appeared on *Partners Against Pain*. One of the consultants was APF's paid employee, Mickie Brown. The consultant's services would be provided in return for a $10,000 consulting fee for APF and $1,500 in honoraria for the spokesperson. All documents used by the consultant in her media appearances would be

reviewed and approved by individuals working for Purdue. It was not until later that APF worried about "how Purdue sees this program fitting in with our [existing] grant request."

172. Given the financial and reputational incentives associated with assisting Purdue in this project and the direct contractual relationship and editorial oversight, APF personnel were acting under Purdue's control at all relevant times with respect to *Partners Against Pain*.

173. APF acquiesced to Purdue's frequent requests that APF provide "patient representatives" for *Partners against Pain*. Moreover, APF staff and board members and Front Groups ACPA and AAPM, among others (such as Dr. Webster), appear on *Inthefaceofpain.com* as "Voices of Hope"—"champions passionate about making a difference in the lives of people who live with pain" and providing "inspiration and encouragement" to pain patients. APF also contracted with Purdue for a project on back pain in which, among other things, it provided a patient representative who agreed to attend a Purdue-run "media training session."

174. According to an Assurance of Voluntary Compliance ("AVC") entered into between the New York Attorney General and Purdue Pharma on August 19, 2015, *Inthefaceofpain.com* received 251,648 page views between March 2014 and March 2015. With the exception of one document linked to the website, *Inthefaceofpain.com* makes no mention of opioid abuse or addiction. Purdue's copyright appears at the bottom of each page of the website, indicating its ownership and control of its content. There is no other indication that 11 of the individuals who provided testimonials on *Inthefaceofpain.com* received payments, according to the AVC, of $231,000 for their

participation in speakers programs, advisory meetings and travel costs between 2008 and 2013. The New York Attorney General found Purdue's failure to disclose its financial connections with these individuals had the potential to mislead consumers.

175. Nowhere was Purdue's influence over APF so pronounced as it was with the APF's "Pain Care Forum" ("PCF"). PCF was and continues to be run not by APF, but by Defendant Purdue's in-house lobbyist, Burt Rosen. As described by a former drug company employee, Rosen exercised full control of PCF, telling them "what to do and how to do it." This control allowed him, in turn, to run APF as, in accordance with Rosen's thinking, "PCF was APF, which was Purdue." PCF meets regularly in-person and via teleconference, and shares information through an email listserv.

176. APF issued education guides for patients, reporters, and policymakers that touted the benefits of opioids for chronic pain and trivialized their risks, particularly the risk of addiction. APF also launched a campaign to promote opioids for returning veterans, which has contributed to high rates of addiction and other adverse outcomes—including death—among returning soldiers. APF also engaged in a significant multimedia campaign—through radio, television and the internet—to educate patients about their "right" to pain treatment, namely opioids. All of the programs and materials were available nationally and were intended to reach County residents.

177. In addition to Perry Fine, Russell Portenoy, and Scott Fishman, who served on APF's Board and reviewed its publications, another board member, Lisa Weiss, was an employee of a public relations firm that worked for both Purdue and APF.

178. In 2009 and 2010, more than 80% of APF's operating budget came from pharmaceutical industry sources. Including industry grants for specific projects, APF received about $2.3 million from industry sources out of total income of about $2.85 million in 2009; its budget for 2010 projected receipts of roughly $2.9 million from drug companies out of total income of about $3.5 million. By 2011, APF was entirely dependent on incoming grants from defendants Purdue, Cephalon, Endo, and others to avoid using its line of credit. As one of its board members, Russell Portenoy, explained, the lack of funding diversity was one of the biggest problems at APF.

179. APF held itself out as an independent patient advocacy organization. It often engaged in grassroots lobbying against various legislative initiatives that might limit opioid prescribing, and thus the profitability of its sponsors. It was often called upon to provide "patient representatives" for Defendants' promotional activities, including for Purdue's *Partners Against Pain* and Janssen's *Let's Talk Pain*. As laid out below, APF functioned largely as an advocate for the interests of Defendants, not patients. Indeed, as early as 2001, Purdue told APF that the basis of a grant was Purdue's desire to "strategically align its investments in nonprofit organizations that share [its] business interests."

180. In practice, APF operated in close collaboration with opioid makers. On several occasions, representatives of the drug companies, often at informal meetings at Front Group conferences, suggested activities and publications APF could pursue. APF then submitted grant proposals seeking to fund these activities and publications, knowing that drug companies would support projects conceived as a result of these communications.

181. APF assisted in other marketing projects for drug companies. One project funded by another drug company—*APF Reporter's Guide: Covering Pain and Its Management* (2008)[61]—recycled text that was originally created as part of the company's training document.

182. The same drug company made general grants, but even then, it directed how APF used them. In response to an APF request for funding to address a potentially damaging state Medicaid decision related to pain medications generally, the company representative responded, "I provided an advocacy grant to APF this year—this would be a very good issue on which to use some of that. How does that work?"

183. The close relationship between APF and the drug company was not unique, but in fact mirrors the relationships between APF and Defendants. APF's clear lack of independence—in its finances, management, and mission—and its willingness to allow Defendants to control its activities and messages, support an inference that each Defendant that worked with APF was able to exercise editorial control over its publications.

184. Indeed, the U.S. Senate Finance Committee began looking into APF in May 2012 to determine the links, financial and otherwise, between the organization and the manufacturers of opioid painkillers. The investigation caused considerable damage to APF's credibility as an objective and neutral third party and Defendants stopped funding it. Within days of being targeted by Senate investigation, APF's board voted

[61] https://assets.documentcloud.org/documents/277606/apf-reporters-guide.pdf (accessed July 12, 2018)

to dissolve the organization and ceased to exist, effective immediately. In 2007, Purdue sponsored FSMB's *Responsible Opioid Prescribing*, which, as described above, deceptively portrayed the risks, benefits, and superiority of opioids to treat chronic pain. *Responsible Opioid Prescribing* also was drafted by Dr. Scott Fishman.

185. Purdue spent $150,000 to help FSMB distribute *Responsible Opioid Prescribing*. The book was distributed nationally

186. The American Academy of Pain Medicine, with the assistance, prompting, involvement, and funding of Defendants, issued treatment guidelines and sponsored and hosted medical education programs essential to Defendants' deceptive marketing of chronic opioid therapy.

187. AAPM has received over $2.2 million in funding since 2009 from opioid manufacturers. AAPM maintains a corporate relations council, whose members pay $25,000 per year (on top of other funding) to participate. The benefits include allowing members to present educational programs at off- site dinner symposia in connection with AAPM's marquee event—its annual meeting held in Palm Springs, California, or other resort locations. AAPM describes the annual event as an "exclusive venue" for offering education programs to doctors.

188. Membership in the corporate relations council also allows drug company executives and marketing staff to meet with AAPM executive committee members in small settings. Defendants Endo, Purdue, Cephalon and Actavis were members of the council and presented deceptive programs to doctors who attended this annual event.

189. AAPM is viewed internally by Endo as "industry friendly," with Endo advisors and speakers among its active members. Endo attended AAPM conferences, funded its CMEs, and distributed its publications. The conferences sponsored by AAPM heavily emphasized sessions on opioids—37 out of roughly 40 at one conference alone. AAPM's presidents have included top industry- supported KOLs Perry Fine, Russell Portenoy, and Lynn Webster. Dr. Webster was even elected president of AAPM while under a DEA investigation. Upon information and belief, another past AAPM president, Dr. Scott Fishman, stated that he would place the organization "at the forefront" of teaching that "the risks of addiction are . . . small and can be managed."[62]

190. AAPM's staff understood that they and their industry funders were engaged in a common practice. Defendants were able to influence AAPM through both their significant and regular funding, and the leadership of pro-opioid KOLs within the organization.

b. Manufacturer Defendants embarked upon a campaign of false, deceptive and unfair assurances grossly overstating the benefits of the opioid drugs.

191. Defendants worked with each other and with the Front Groups and KOLs they funded and directed to carry out a common scheme to deceptively present the risks, benefits, and superiority of opioids to treat chronic pain.

192. Defendants acted through and with the same network of Front Groups, funded the same KOLs, and often used the very same language and format to disseminate the

[62] Interview by Paula Moyer with Scott M. Fishman, M.D., Professor of Anesthesiology and Pain Medicine, Chief of the Division of Pain Medicine, Univ. of Cal., Davis (2005).

same deceptive messages. These KOLs have worked reciprocally with Defendants to promote misleading messaging regarding the appropriate use of opioids to treat chronic pain. Although participants knew this information was false and misleading, these misstatements were nevertheless disseminated to Palm Beach County prescribers and patients.

193. One vehicle for their collective collaboration was Pain Care Forum ("PCF"). PCF began in 2004 as an APF project with the stated goals of offering "a setting where multiple organizations can share information" and to "promote and support taking collaborative action regarding federal pain policy issues." APF President Will Rowe described the Forum as "a deliberate effort to positively merge the capacities of industry, professional associations, and patient organizations."

194. PCF is comprised of representatives from opioid manufacturers and distributors (including Cephalon, Endo, Janssen, and Purdue); doctors and nurses in the field of pain care; professional organizations (*e.g.*, American Academy of Pain Management, APS, and American Society of Pain Educators); patient advocacy groups (*e.g.*, APF and ACPA); and other like-minded organizations (*e.g.*, FSMB and Wisconsin Pain & Policy Studies Group), almost all of which received substantial funding from Defendants.

195. PCF, for example, developed and disseminated "consensus recommendations" for a Risk Evaluation and Mitigation Strategy ("REMS") for long-acting opioids that the FDA mandated in 2009 to communicate the risks of opioids to prescribers and

patients.[63] This was critical as a REMS that went too far in narrowing the uses or benefits, or highlighting the risks of chronic opioid therapy, would deflate Defendants' marketing efforts. The recommendations—drafted by Will Rowe of APF—claimed that opioids were "essential" to the management of pain, and that the REMS "should acknowledge the importance of opioids in the management of pain and should not introduce new barriers."[64] Defendants worked with PCF members to limit the reach and manage the message of the REMS, which enabled them to maintain, and not undermine, their deceptive marketing of opioids for chronic pain.

196. Some illustrative examples of the Manufacturer Defendants' false claims are:

a. Upon information and belief, Actavis distributed an advertisement claiming that the use of Kadian to treat chronic pain would allow patients to return to work, relieve "stress on your body and your mental health," and help patients enjoy their lives.

b. Endo distributed advertisements that claimed that the use of Opana ER for chronic pain would allow patients to perform demanding tasks like construction work or work as a chef and portrayed seemingly healthy, unimpaired subjects.

c. Janssen sponsored and edited a patient education guide entitled Finding Relief Pain Management for Older Adults (2009) - which states as "a fact" that "opioids may make it easier for people to live normally." The guide lists

[63] The FDA can require a drug maker to develop a REMS—which could entail (as in this case) an education requirement or distribution limitation—to manage serious risks associated with a drug.

[64] Defendants also agreed that short-acting opioids should also be included in REMS as not to disadvantage the long-acting, branded drugs.

expected functional improvements from opioid use, including sleeping through the night, returning to work, recreation, sex, walking, and climbing stairs.

d. Janssen promoted Ultracet for everyday chronic pain and distributed posters, for display in doctors' offices, of presumed patients in active professions; the caption read, "Pain doesn't fit into their schedules."

e. Upon information and belief, Purdue ran a series of advertisements for OxyContin in 2012 in medical journals entitled "Pain vignettes," which were case studies featuring patients with pain conditions persisting over several months and recommending OxyContin for them. The ads implied that OxyContin improves patients' function.

f. Responsible Opioid Prescribing (2007), sponsored and distributed by Cephalon, Endo and Purdue, taught that relief of pain by opioids, by itself, improved patients' function.

g. Cephalon and Purdue sponsored APF's Treatment Options: A Guide for People Living with Pain (2007), which counseled patients that opioids "give [pain patients] a quality of life we deserve."[65] This publication is still available online.

h. Endo's NIPC website "PainKnowledge" claimed in 2009, upon information and belief, that with opioids, "your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse."

[65] Am. Pam Found., Treatment Options: A Guide for People Living in Pain (2007) [hereinafter APF, Treatment Options], https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf.

Elsewhere, the website touted improved quality of life (as well as "improved function") as benefits of opioid therapy. The grant request that Endo approved for this project specifically indicated NIPC's intent to make misleading claims about function, and Endo closely tracked visits to the site.

i. Endo was the sole sponsor, through NIPC, of a series of CMEs entitled "Persistent Pain in the Older Patient." Upon information and belief, a CME disseminated via webcast claimed that chronic opioid therapy has been "shown to reduce pain and improve depressive symptoms and cognitive functioning."

j. Janssen sponsored and funded a multimedia patient education campaign called "Let's Talk Pain." One feature of the campaign was to complain that patients were under-treated. In 2009, upon information and belief, a Janssen-sponsored website, part of the "Let's Talk Pain" campaign, featured an interview edited by Janssen claiming that opioids allowed a patient to "continue to function."

k. Purdue sponsored the development and distribution of APF's A Policymaker's Guide to Understanding Pain & Its Management, which claimed that "[m]ultiple clinical studies" have shown that opioids are effective in improving "[d]aily function," "[p]sychological health," and "[o]verall health-related quality of life for chronic pain."[66]The Policymaker's Guide was originally published in 2011.[67]

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[66] Am. Pain Found., A Policymaker's Guide to Understanding Pain and Its Management 6 (2011) [hereinafter APF, Policymaker's Guide], http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf (last accessed Jul. 12, 2018)

[67] *Id.*

l. Purdue's, Cephalon's, Endo's, and Janssen's sales representatives have conveyed and continue to convey the message that opioids will improve patient function.

197. As the FDA and other agencies have made clear for years, these claims have no support in the scientific literature.

198. There are eight primary misleading and unfounded representations. Defendants and the third parties with which they teamed:

a. misrepresented that opioids improve function;

b. misrepresented that opioids are safe and effective for long-term use;

c. concealed the link between long-term use of opioids and addiction;

d. misrepresented that addiction risk can be managed;

e. masked the signs of addiction by calling them "pseudoaddiction";

f. falsely claimed withdrawal is easily managed;

g. misrepresented or omitted the greater dangers from higher doses of opioids; and deceptively minimized the adverse effects of opioids and overstated the risks of NSAIDs.

199. In addition to these misstatements, Purdue purveyed an eighth deception that OxyContin provides a full 12 hours of pain relief.

200. Exacerbating each of these misrepresentations and deceptions was the collective effort of Defendants and third parties to hide from the medical community

the fact that the FDA "is not aware of adequate and well-controlled studies of opioid use longer than 12 weeks."[68]

i. "Improved Function"

201. Each of the following materials was created with the expectation that, by instructing patients and prescribers that opioids would improve patients' function and quality of life, patients would demand opioids and doctors would prescribe them. These claims also encouraged doctors to continue opioid therapy in the belief that failure to improve pain, function, or quality of life, could be overcome by increasing doses or prescribing supplemental short-acting opioids to take on an as-needed basis for breakthrough pain.

202. However, not only is there no evidence of improvement in long-term functioning, a 2006 study-of-studies found that "[f]or functional outcomes . . . other analgesics were significantly more effective than were opioids."[69] Studies of the use of opioids in chronic conditions for which they are commonly prescribed, such as low back pain, corroborate this conclusion and have failed to demonstrate an improvement in patients' function. Instead, research consistently shows that long-term opioid therapy for patients who have lower back injuries does not cause patients to return to work or physical activity.[70] Indeed, one Defendant's own internal marketing plans

[68] Letter from Janet Woodcock, M.D., Dir., Ctr. for Drug Eval. & Res., to Andrew Kolodny, M.D., Pres. Physicians for Responsible Opioid Prescribing, Re Docket No. FDA-2012-P-0818 (Sept. 10, 2013).

[69] Andrea D. Furlan et al., Opioids for chronic noncancer pain: a meta-analysis of effectiveness and side effects, 174(11) Can. Med. Ass'n J. 1589-1594 (2006). This study revealed that efficacy studies do not typically include data on opioid addiction, such that, if anything, the data overstate effectiveness.

[70] Moreover, users of opioids had the highest increase in the number of headache days per month, scored significantly higher on the Migraine Disability Assessment (MIDAS), and had higher rates of depression, compared to non-opioid users. They also were more likely to

characterized functional improvement claims as "aspirational." Another acknowledged in 2012 that "[s]ignificant investment in clinical data [was] needed" to establish opioids' effect on mitigating quality of life issues, like social isolation.

203. The long-term use of opioids carries a host of serious side effects, including addiction, mental clouding and confusion, sleepiness, hyperalgesia, and immune-system and hormonal dysfunction that degrade, rather than improve, patients' ability to function. Defendants often omitted these adverse effects as well as certain risks of drug interactions from their publications.

204. Yet each of the following statements by Defendants, suggests that the long-term use of opioids improve patients' function and quality of life, and that scientific evidence supports this claim:

a. Documents from a 2010 sales training indicate that Actavis trained its sales force to instruct prescribers that "**most** chronic benign pain patients do have **markedly improved ability to function** when maintained on chronic opioid therapy." (Emphasis added.)

b. Documents from a 2010 sales training indicate that Actavis trained its sales force that increasing and restoring function is an expected outcome of chronic Kadian therapy, including physical, social, vocational, and recreational function.

c. Actavis distributed a product advertisement that claimed that use of Kadian to treat chronic pain would allow patients to return to work, relieve "stress on your

experience sleepiness, confusion, and rebound headaches, and reported a lower quality of life than patients taking other medications.

body and your mental health," and cause patients to enjoy their lives. The FDA warned Actavis that such claims were misleading, writing: "We are not aware of substantial evidence or substantial clinical experience demonstrating that the magnitude of the effect of the drug has in alleviating pain, taken together with any drug-related side effects patients may experience . . . results in any overall positive impact on a patient's work, physical and mental functioning, daily activities, or enjoyment of life."[71]

d. Actavis sales representatives told Charleston County prescribers that prescribing Actavis's opioids would improve their patients' ability to function and improve their quality of life.

e. Cephalon sponsored the FSMB's Responsible Opioid Prescribing (2007), which taught that relief of pain itself improved patients' function. *Responsible Opioid Prescribing* explicitly describes functional improvement as the goal of a "long-term therapeutic treatment course." Cephalon also spent $150,000 to purchase copies of the book in bulk and distributed the book through its pain sales force to 10,000 prescribers and 5,000 pharmacists.

f. Cephalon sponsored the American Pain Foundation's *Treatment Options: A Guide for People Living with Pain* (2007), which taught patients that opioids, when used properly "give [pain patients] a quality of life we deserve." [72] The

[71] Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Commc'ns, to Doug Boothe, CEO, Actavis Elizabeth LLC (Feb. 18, 2010), available at (https://www.fdanews.com/ext/resources/files/archives/a/ActavisElizabethLLC.pdf)
[72] Am. Pam Found., *Treatment Options: A Guide for People Living in Pain* (2007) [hereinafter APF, Treatment Options], https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf.

Treatment Options guide notes that non-steroidal anti-inflammatory drugs have greater risks associated with prolonged duration of use, but there was no similar warning for opioids. APF distributed 17,200 copies in one year alone, according to its 2007 annual report. The publication is also currently available online.

g. Cephalon sponsored a CME written by key opinion leader Dr. Lynn Webster, titled *Optimizing Opioid Treatment for Breakthrough Pain*, which was offered online by Medscape, LLC from September 28, 2007, to December 15, 2008. The CME taught that Cephalon's Actiq and Fentora improve patients' quality of life and allow for more activities when taken in conjunction with long- acting opioids.

h. Cephalon sales representatives told Charleston County prescribers that opioids would increase patients' ability to function and improve their quality of life.

i. Endo sponsored a website, painknowledge.com, through APF and NIPC, which, in 2009, claimed that with opioids, "your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse." Endo continued to provide funding for this website through 2012, and closely tracked unique visitors to it.

j. A CME sponsored by Endo, titled *Persistent Pain in the Older Patient*, taught that chronic opioid therapy has been "shown to reduce pain and improve depressive symptoms and cognitive functioning."

k. Endo distributed handouts to prescribers that claimed that use of Opana ER to treat chronic pain would allow patients to perform work as a chef. This

flyer also emphasized Opana ER's indication without including equally prominent disclosure of the "moderate to severe pain" qualification.[73]

l. Endo's sales force distributed FSMB's *Responsible Opioid Prescribing* (2007), which taught that relief of pain itself improved patients' function. *Responsible Opioid Prescribing* explicitly describes functional improvement as the goal of a "long-term therapeutic treatment course."

m. Endo provided grants to APF to distribute *Exit Wounds* to veterans, which taught that opioid medications "*increase* your level of functioning" (emphasis in the original). *Exit Wounds* also omits warnings of the risk of interactions between opioids and benzodiazepines, which would increase fatality risk. Benzodiazepines are frequently prescribed to veterans diagnosed with post- traumatic stress disorder.

n. Endo sales representatives told prescribers that opioids would increase patients' ability to function and improve their quality of life by helping them become more physically active and return to work.

o. Janssen sponsored a patient education guide titled *Finding Relief: Pain Management for Older Adults* (2009), which its personnel reviewed and approved, and its sales force distributed. This guide features a man playing golf on the cover and lists examples of expected functional improvement from opioids, like sleeping through the night, returning to work, recreation, sex, walking, and climbing stairs. The guide states as a "fact" that "opioids

[73] FDA regulations require that warnings or limitations be given equal prominence in disclosure, and failure to do so constitutes "misbranding" of the product. 21 C.F.R. § 202.1(e)(3); *see also* 21 U.S.C. §331(a).

may make it *easier* for people to live normally" (emphasis in the original). The myth/fact structure implies authoritative backing for the claims that does not exist. The targeting of older adults also ignored heightened opioid risks in this population.

p. Janssen sponsored, developed, and approved content of a website, *Let's Talk Pain* in 2009, acting in conjunction with the APF, AAPM, and ASPMN, whose participation in *Let's Talk Pain* Janssen financed and orchestrated. This website featured an interview, which was edited by Janssen personnel, claiming that opioids were what allowed a patient to "continue to function," inaccurately implying her experience would be representative.

q. Janssen provided grants to APF to distribute *Exit Wounds* to veterans, which taught that opioid medications "*increase* your level of functioning" (emphasis in the original). *Exit Wounds* also omits warnings of the risk of interactions between opioids and benzodiazepines, which would increase fatality risk. Benzodiazepines are frequently prescribed to veterans diagnosed with post-traumatic stress disorder.

r. Janssen sales representatives told prescribers that opioids would increase patients' ability to function and improve their quality of life by helping them become more physically active and return to work.

s. Purdue ran a series of advertisements for OxyContin in 2012 in medical journals titled "Pain vignettes," which were case studies featuring patients, each with pain conditions persisting over several months, recommending

OxyContin for each. One such patient, "Paul," is described as a "54-year-old writer with osteoarthritis of the hands," and the vignettes imply that an OxyContin prescription will help him work more effectively.

t. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which inaccurately claimed that "multiple clinical studies" had shown that opioids are effective in improving daily function, psychological health, and health-related quality of life for chronic pain patients." [74] The sole reference for the functional improvement claim noted the absence of long-term studies and actually stated: "For functional outcomes, the other analgesics were significantly more effective than were opioids." The *Policymaker's Guide* is still available online.

u. Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which counseled patients that opioids, when used properly, "give [pain patients] a quality of life we deserve." APF distributed 17,200 copies in one year alone, according to its 2007 annual report. The guide is currently available online.[75]

v. Purdue sponsored APF's *Exit Wounds* (2009), which taught veterans that opioid medications "increase your level of functioning." *Exit Wounds* also omits warnings of the risk of interactions between opioids and benzodiazepines, which would increase fatality risk. Benzodiazepines are

[74] APF, Policymaker's Guide, http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf (accessed July. 12, 2018)
[75] Am. Pam Found., *Treatment Options: A Guide for People Living in Pain* (2007) [hereinafter APF, Treatment Options], https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf.

frequently prescribed to veterans diagnosed with post-traumatic stress disorder.

w. Purdue sponsored the FSMB's *Responsible Opioid Prescribing* (2007), which taught that relief of pain itself improved patients' function. *Responsible Opioid Prescribing* explicitly describes functional improvement as the goal of a "long-term therapeutic treatment course." Purdue also spent over $100,000 to support distribution of the book.

x. In 2012, Purdue disseminated a mailer to doctors titled "Pain vignettes." These "vignettes" consisted of case studies describing patients with pain conditions that persisted over a span of several months. One such patient, "Paul," is described as a "54-year-old writer with osteoarthritis of the hands," and the vignettes imply that an OxyContin prescription will help him work. None of these ads, however, disclosed the truth—that there is no evidence that opioids improve patients' lives and ability to function and that there was substantial evidence to the contrary.

y. Purdue sales representatives told prescribers that opioids would increase patients' ability to function and improve their quality of life.

ii. Long-Term Use of Opioids

205. There are no controlled studies of the use of opioids beyond 16 weeks, and no evidence that opioids improve patients' pain and function long-term. The first random, placebo- controlled studies appeared in the 1990s, and revealed evidence only for short-term efficacy and only in a minority of patients.

206. A 2004 report reviewed 213 randomized, controlled trials of treatments for cancer pain and showed that, while opioids had short-term efficacy, the data was insufficient to

establish long-term effectiveness. Subsequent reviews of the use of opioids for cancer and non-cancer pain consistently note the lack of data to assess long-term outcomes. For example, a 2007 systematic review of opioids for back pain concluded that opioids have limited, if any, efficacy for back pain and that evidence did not allow judgments regarding long-term use. Similarly, a 2011 systematic review of studies for non-cancer pain found that evidence of long-term efficacy is poor. One year later, a similar review reported poor evidence of long-term efficacy for morphine, tramadol, and oxycodone, and fair evidence for transdermal fentanyl (approved only for use for cancer pain).

207. On the contrary, evidence exists to show that opioid drugs are not effective to treat chronic pain, and may worsen patients' health. A 2006 study-of-studies found that opioids as a class did not demonstrate improvement in functional outcomes over other non-addicting treatments. Most notably, it stated: "For functional outcomes, the other analgesics were significantly more effective than were opioids." Another review of evidence relating to the use of opioids for chronic pain found that up to 22.9% of patients in opioid trials dropped out before the study began because of the intolerable effects of opioids, and that the evidence of pain relief over time was weak.

208. Endo's own research shows that patients taking opioids, as opposed to other prescription pain medicines, report higher rates of obesity (30% to 39%); insomnia (9% to 22%); and self-described fair or poor health (24% to 34%).

209. Increasing duration of opioid use is strongly associated with an increasing prevalence of mental health conditions (depression, anxiety, post-traumatic stress disorder, or substance abuse), increased psychological distress, and greater health care utilization.

210. As a pain specialist noted in an article titled Are We Making Pain Patients Worse?, "[O]pioids may work acceptably well for a while, but over the long term, function generally declines, as does general health, mental health, and social functioning. Over time, even high doses of potent opioids often fail to control pain, and these patients are unable to function normally."

211. This is true both generally and for specific pain-related conditions. Studies of the use of opioids long-term for chronic lower back pain have been unable to demonstrate an improvement in patients' function. Conversely, research consistently shows that long-term opioid therapy for patients who have lower back injuries does not help patients return to work or to physical activity. This is due partly to addiction and other side effects.

212. As many as 30% of patients who suffer from migraines have been prescribed opioids to treat their headaches. Users of opioids had the highest increase in the number of headache days per month, scored significantly higher on the Migraine Disability Assessment (MIDAS), and had higher rates of depression, compared to non-opioid users. A survey by the National Headache Foundation found that migraine patients who used opioids were more likely to experience sleepiness, confusion, and rebound headaches, and reported a lower quality of life than patients taking other medications.

213. The lack of evidence for the efficacy of opioid use long-term has been well-documented nationally in the context of workers' compensation claims, where some of the most detailed data exists. Claims involving workers who take opioids are almost four times as likely to reach costs of over $100,000 than claims without opioids, as these patients suffer greater side effects and are slower to return to work. Even adjusting for

injury severity and self-reported pain score, taking an opioid for more than seven days and receiving more than one opioid prescription increased the risk that the patient would be on work disability one year later. A prescription for opioids, as the first treatment for a workplace injury, doubled the average length of the claim.

iii. "Low risk of Addiction"

214. Some illustrative examples of the Manufacturer Defendants' false, deceptive, and unfair claims about the purportedly low risk of addiction include:

a. Actavis's predecessor caused a patient education brochure, Managing Chronic Back Pain, to be distributed beginning in 2003 that admitted that opioid addiction is possible, but falsely claimed that it is "less likely if you have never had an addiction problem." Based on Actavis's acquisition of its predecessor's marketing materials along with the rights to Kadian, it appears that Actavis continued to use this brochure in 2009 and beyond.

b. Cephalon and Purdue sponsored APF's Treatment Options: A Guide for People Living with Pain (2007), which suggested that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining duplicative opioid prescriptions from multiple sources, or theft. This publication is still available online.[76]

c. Endo sponsored a website, "PainKnowledge," which, upon information and belief, claimed in 2009 that "[p]eople who take opioids as prescribed usually do not become addicted." Upon information and belief, another Endo website, PainAction.com, stated "Did you know? Most chronic pain patients do not

[76] APF, Treatment Options, https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf.

become addicted to the opioid medications that are prescribed for them." Endo also distributed an "Informed Consent" document on PainAction.com that misleadingly suggested that only people who "have problems with substance abuse and addiction" are likely to become addicted to opioid medications.

d. Upon information and belief, Endo distributed a pamphlet with the Endo logo entitled Living with Someone with Chronic Pain, which stated that: "Most health care providers who treat people with pain agree that most people do not develop an addiction problem."

e. Janssen reviewed, edited, approved, and distributed a patient education guide entitled Finding Relief Pain Management for Older Adults (2009), which described as "myth" the claim that opioids are addictive, and asserted as fact that "[m]any studies show that opioids are rarely addictive when used properly for the management of chronic pain."

f. Janssen currently runs a website, Prescriberesponsibly.com (last updated July 2, 2015), which claims that concerns about opioid addiction are "overestimated."

g. Purdue sponsored APF's A Policymaker's Guide to Understanding Pain & Its Management, which claims that less than 1 % of children prescribed opioids will become addicted and that pain is undertreated due to "[m]isconceptions about opioid addiction." [77]

h. Consistent with the Manufacturer Defendants' published marketing materials, upon information and belief, detailers for Purdue, Endo, Janssen, and Cephalon

[77] APF, Policymaker's Guide, http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf (accessed July 12, 2018)

minimized or omitted any discussion with doctors of the risk of addiction; misrepresented the potential for abuse of opioids with purportedly abuse-deterrent formulations; and routinely did not correct the misrepresentations noted above.

i. Sales representatives for Actavis, Endo, Janssen, and Purdue promoted their drugs as having "steady-state" properties with the intent and expectation that prescribers would understand this to mean that their drugs caused less of a rush or a feeling of euphoria, which can trigger abuse and addiction.

j. Endo actively promoted its reformulated Opana ER on the basis that it was "designed to be crush-resistant," suggesting both (a) that Endo had succeeded in making the drug harder to adulterate, and (b) that it was less addictive, in consequence. In fact, however, Endo knew that "the clinical significance of INTAC Technology or its impact on abuse/misuse has not been established for Opana ER" and that Opana ER could still be ground and cut into small pieces by those looking to abuse the drug.

k. Janssen denied that Nucynta ER was an opioid and claimed that it was not addictive.

l. Purdue claimed that its opioids were not favored by addicts and did not produce a buzz, all of which falsely suggested that its opioids were less likely to be abused or addictive.

215. In addition to denying or minimizing the risk of addiction and abuse generally, Defendants also falsely claimed that their particular drugs were safer, less addictive, and less likely to be abused or diverted than their competitors' or predecessor drugs. In making these claims, Defendants said or implied that because

their drug had a "steady-state" and did not produce peaks and valleys, which cause drug-seeking behavior—either to obtain the high or avoid the low—it was less likely to be abused or addicting. Endo also asserted in particular that, because a reformulation of Opana ER was (or was designed to be) abuse-deterrent or tamper-resistant, patients were less likely to become addicted to it. Defendants had no evidence to support any of these claims, which, by FDA regulation, must be based on head-to-head trials;[78] the claims also were false and misleading in that they misrepresented the risks of both the particular drug and opioids as a class.

216. Further, rather than honestly disclose the risk of addiction, Defendants, and the third parties they directed and assisted and whose materials they distributed, attempted to portray those who were concerned about addiction as unfairly denying treatment to needy patients. To increase pressure on doctors to prescribe chronic opioid therapy, Defendants turned the tables; it was doctors who fail to treat their patients' chronic pains with opioids—not doctors who cause their patients to become addicted to opioids—who are failing their patients (and subject to discipline). Defendants and their third-party allies claimed that purportedly overblown worries about addiction cause pain to be under-treated and opioids to be over-regulated and under-prescribed. This mantra of under-treated pain and under-used drugs reinforced Defendants' messages that the risks of addiction and abuse were not significant and were overblown.

iv. Creating the Phrase "Pseudoaddiction"

[78] *See* Guidance for Industry, "Abuse-Deterrent Opioids—Evaluation and Labeling," April 2015 (describing requirements for premarket and postmarket studies).

217. In addition to mischaracterizing the highly addictive nature of the drugs they were pushing, the Manufacturer Defendants also fostered a fundamental misunderstanding of the signs of addiction. Specifically, the Manufacturer Defendants misrepresented, to doctors and patients, that warning signs and/or symptoms of addiction were, instead, signs of undertreated pain (i.e. pseudo addiction) - and instructed doctors to increase the opioid prescription dose for patients who were already in danger.

218. To this end, one of Purdue's employees, Dr. David Haddox, invented a phenomenon called "pseudoaddiction." KOL Dr. Portenoy popularized the term. Examples of the false, misleading, deceptive, and unfair statements regarding pseudoaddiction include:

a. Documents from a 2010 sales training indicate that Actavis trained its sales force to instruct physicians that aberrant behaviors like self-escalation of doses constituted "pseudoaddiction."

b. Cephalon sponsored FSMB's *Responsible Opioid Prescribing* (2007), which taught that behaviors such as "requesting drugs by name," "demanding or manipulative behavior," seeing more than one doctor to obtain opioids, and hoarding are all signs of "pseudoaddiction." Cephalon also spent $150,000 to purchase copies of the book in bulk and distributed it through its pain sales force to 10,000 prescribers and 5,000 pharmacists.

c. From 2009 to 2011 Janssen's website, *Let's Talk Pain*, stated that "pseudoaddiction . . . refers to patient behaviors that may occur when pain is under-treated" and that "[p]seudoaddiction is different from true addiction

because such behaviors can be resolved with effective pain management." (emphasis added).

d. Endo distributed copies of a book by KOL Dr. Lynn Webster entitled *Avoiding Opioid Abuse While Managing Pain* (2007). Endo's internal planning documents describe the purpose of distributing this book as to "[i]ncrease the breadth and depth of the Opana ER prescriber base." The book claims that when faced with signs of aberrant behavior, the doctor should regard it as "pseudoaddiction" and thus, increasing the dose *in most cases. . . Should be the clinician's first response*." (emphasis added).

e. Endo spent $246,620 to buy copies of FSMB's *Responsible Opioid Prescribing* (2007), which was distributed by Endo's sales force. This book asserted that behaviors such as "requesting drugs by name," "demanding or manipulative behavior," seeing more than one doctor to obtain opioids, and hoarding, are all signs of "pseudoaddiction."

f. Purdue published a prescriber and law enforcement education pamphlet in 2011 entitled *Providing Relief, Preventing Abuse*, which described "pseudoaddiction" as a concept that "emerged in the literature to describe the inaccurate interpretation of [drug-seeking behaviors] in patients who have pain that has not been effectively treated."

g. Purdue distributed to physicians, at least as of November 2006, and posted on its unbranded website, *Partners Against Pain*, a pamphlet copyrighted 2005 and titled *Clinical Issues in Opioid Prescribing*. This pamphlet included a list of conduct, including "illicit drug use and deception" it defined as

indicative of "pseudoaddiction" or untreated pain. It also states:

"Pseudoaddiction is a term which has been used to describe patient behaviors that may occur when *pain is undertreated*. . . . Even such behaviors as illicit drug use and deception can occur in the patient's efforts to obtain relief. Pseudoaddiction can be *distinguished from true addiction* in that the behaviors resolve when the pain is effectively treated." (emphasis added.)

h. Purdue sponsored FSMB's *Responsible Opioid Prescribing* (2007), which taught that behaviors such as "requesting drugs by name, "demanding or manipulative behavior," seeing more than one doctor to obtain opioids, and hoarding, are all signs of "pseudoaddiction." Purdue also spent over $100,000 to support distribution of the book.

i. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which states: "Pseudo-addiction describes patient behaviors that may occur when *pain is undertreated*. . . . Pseudo-addiction can be distinguished from true addiction in that this behavior ceases when pain is effectively treated."[79] (Emphasis added.)

219. In the 2016 CDC Guideline, the CDC rejects the validity of the pseudoaddiction fallacy invented by a Purdue employee as a reason to push more opioid drugs onto already addicted patients.

v. False Instructions about Screening and Abuse Deterrents

220. Manufacturer Defendants' made false statements that addiction risk screening tools, patient contracts, urine drug screens, and similar strategies allow them to reliably

[79] APF, Policymaker's Guide, http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf (last accessed Jul. 12, 2018)

identify and safely prescribe opioids to patients predisposed to addiction. These misrepresentations were especially insidious because the Manufacturer Defendants aimed them at general practitioners and family doctors who lack the time and expertise to closely manage higher-risk patients on opioids.

221. The Manufacturer Defendants' misrepresentations made these doctors feel more comfortable prescribing opioids to their patients, and patients more comfortable starting on opioid therapy for chronic pain. Illustrative examples include:

a. Documents from a 2010 sales training indicate that Actavis trained its sales force that prescribers can use risk screening tools to limit the development of addiction.

b. Cephalon sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which taught patients that "opioid agreements" between doctors and patients can "ensure that you take the opioid as prescribed."[80]

c. Endo paid for a 2007 supplement[81] available for continuing education credit in the Journal of Family Practice. This publication, titled Pain Management Dilemmas in Primary Care: Use of Opioids, recommended screening patients using tools like the Opioid Risk Tool or the Screener and Opioid Assessment for Patients with Pain, and advised that patients at high risk of addiction could safely (e.g., without becoming addicted) receive chronic opioid therapy using a "maximally structured approach" involving toxicology screens and pill counts.

[80] Am. Pam Found., *Treatment Options: A Guide for People Living in Pain* (2007) [hereinafter APF, Treatment Options], https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf.

[81] The Medical Journal, *The Lancet found that all of the supplement papers it received failed peer-review. Editorial, "The Perils of Journal and Supplement Publishing,"* 375 The Lancet 9712 (347) 2010.

d. Purdue, upon information and belief, sponsored a 2011 webinar, Managing Patient's Opioid Use: Balancing the Need and Risk, which claimed that screening tools, urine tests, and patient agreements prevent "overuse of prescriptions" and "overdose deaths."

e. Purdue's unbranded website, In the Face of Pain (inthefaceofpain.com) states that policies that "restrict[] access to patients with pain who also have a history of substance abuse" and "requiring special government-issued prescription forms for the only medications that are capable of relieving pain that is severe" are "at odds with" best medical practices.[82]

f. In 2011, Purdue published a prescriber and law enforcement education pamphlet titled *Providing Relief, Preventing Abuse*, which deceptively portrayed the signs—and therefore the prevalence— of addiction. However, Purdue knew, as described above, that OxyContin was used non-medically by injection less than less than 17% of the time. Yet, *Providing Relief, Preventing Abuse* prominently listed side effects of injection like skin popping and track marks as "Indications of Possible Drug Abuse"— downplaying much more prevalent signs of addiction associated with OxyContin use such as asking for early refills, making it seem as if addiction only occurs when opioids are taken illicitly.

g. As recently as 2015, upon information and belief, Purdue has represented in scientific conferences that "bad apple" patients - and not opioids - are the source

[82] See In the Face of Pain Fact Sheet: Protecting Access to Pain Treatment, Purdue Pharma L.P. (Resources verified Mar. 2012),www.inthefaceofpain.com/content/uploads/2011/12/factsheet_ProtectingAccess.pdf (deactivated).

of the addiction crisis and that once those "bad apples" are identified, doctors can safely prescribe opioids without causing addiction.

222. The 2016 CDC Guideline confirms the falsity of these claims. The Guideline explains that there are no studies assessing the effectiveness of risk mitigation strategies "for improving outcomes related to overdose, addiction, abuse or misuse." [83]

vi. False Claims Related to Management of Withdrawal

223. Defendants and their third-party allies promoted the false and misleading messages below with the intent and expectation that, by misrepresenting the difficulty of withdrawing from opioids, prescribers and patients would be more likely to start chronic opioid therapy and would fail to recognize the actual risk of addiction.

224. In an effort to underplay the risk and impact of addiction, Defendants and their third- party allies frequently claim that, while patients become "physically" dependent on opioids, physical dependence can be addressed by gradually tapering patients' doses to avoid the adverse effects of withdrawal. They fail to disclose the extremely difficult and painful effects that patients can experience when they are removed from opioids—effects that also make it less likely that patients will be able to stop using the drugs.

225. In reality, withdrawal is prevalent in patients after more than a few weeks of therapy. Common symptoms of withdrawal include: severe anxiety, nausea, vomiting, headaches, agitation, insomnia, tremors, hallucinations, delirium, and pain. Some symptoms may persist for months, or even years, after a complete withdrawal

[83] Deborah Dowell *et al*., CDC Guideline for Prescribing Opioids for Chronic Pain-United States, 2016, Morbidity & Mortality Wkly. Rep., Mar. 18, 2016, at 15 [hereinafter 2016 CDC Guideline], https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm (accessed July 13, 2018).

from opioids, depending on how long the patient had been using opioids. Withdrawal symptoms trigger a feedback loop that drives patients to seek opioids, contributing to addiction.

226. Each of the publications and statements below falsely states or suggests that withdrawal from opioids was not a problem and they should not be hesitant about prescribing or using opioids:

a. Documents from a 2010 sales training indicate that Actavis trained its sales force that discontinuing opioid therapy can be handled "simply" and that it can be done at home. Actavis's sales representative training claimed opioid withdrawal would take only a week, even in addicted patients.

b. A CME sponsored by Endo, titled *Persistent Pain in the Older Adult*, taught that withdrawal symptoms can be avoided entirely by tapering the dose by 10-20% per day for ten days.

c. A Janssen PowerPoint presentation used for training its sales representatives titled "Selling Nucynta ER" indicates that the "low incidence of withdrawal symptoms" is a "core message" for its sales force. This message is repeated in numerous Janssen training materials between 2009 and 2011. The studies supporting this claim did not describe withdrawal symptoms in patients taking Nucynta ER beyond 90 days or at high doses and would therefore not be representative of withdrawal symptoms in the chronic pain population. Patients on opioid therapy long-term and at high doses will have a harder time discontinuing the drugs and are more likely to experience withdrawal symptoms. In addition, in claiming a low rate of withdrawal symptoms,

Janssen relied upon a study that only began tracking withdrawal symptoms in patients two to four days after discontinuing opioid use; Janssen knew or should have known that these symptoms peak earlier than that for most patients. Relying on data after that initial window painted a misleading picture of the likelihood and severity of withdrawal associated with chronic opioid therapy. Janssen also knew or should have known that the patients involved in the study were not on the drug long enough to develop rates of withdrawal symptoms comparable to rates of withdrawal suffered by patients who use opioids for chronic pain—the use for which Janssen promoted Nucynta ER.

d. Janssen sales representatives told prescribers that patients on Janssen's drugs were less susceptible to withdrawal than those on other opioids.

e. Purdue sponsored *APF's A Policymaker's Guide to Understanding Pain & Its Management*, which taught that "Symptoms of physical dependence can often be ameliorated by gradually decreasing the dose of medication during discontinuation," but did not disclose the significant hardships that often accompany cessation of use.[84]

f. Purdue sales representatives told prescribers that the effects of withdrawal from opioid use can be successfully managed.

[84] APF, Policymaker's Guide, http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf (accessed July 12, 2018)

g. Purdue sales representatives told prescribers that the potential for withdrawal on Butrans was low due to Butrans's low potency and its extended release mechanism.

vii. False Claims that Increased Dosing Posed no Significant Increased Risks

227. Each of the following misrepresentations was created with the intent and expectation that, by misrepresenting and failing to disclose the known risks of high dose opioids, prescribers and patients would be more likely to continue to prescribe and use opioids, even when they were not effective in reducing patients' pain, and not to discontinue opioids even when tolerance required them to reach even higher doses.

228. Defendants and their third-party allies claimed that patients and prescribers could increase doses of opioids indefinitely without added risk, even when pain was not decreasing or when doses had reached levels that were "frighteningly high," suggesting that patients would eventually reach a stable, effective dose. Each of Defendants' claims also omitted warnings of increased adverse effects that occur at higher doses, and misleadingly suggested that there was no greater risk to higher dose opioid therapy.

229. These claims are false. Patients receiving high doses of opioids as part of long-term opioid therapy are three to nine times more likely to suffer an overdose from opioid-related causes than those on low doses. As compared to available alternative pain remedies, scholars have suggested that tolerance to the respiratory depressive effects of opioids develops at a slower rate than tolerance to analgesic effects. Accordingly, the practice of continuously escalating doses to match pain tolerance can, in fact, lead to overdose even where opioids are taken as recommended. The

FDA has itself acknowledged that available data suggest a relationship between increased doses and the risk of adverse effects. Moreover, it is harder for patients to terminate use of higher-dose opioids without severe withdrawal effects, which contributes to a cycle of continued use, even when the drugs provide no pain relief and are causing harm—the signs of addiction.

230. Each of the following claims suggests that high-dose opioid therapy is safe:

a. Documents from a 2010 sales training indicate that Actavis trained its sales force that "individualization" of opioid therapy depended on increasing doses "until patient reports adequate analgesia" and to "set dose levels on [the] basis of patient need, not on [a] predetermined maximal dose." Actavis further counseled its sales representatives that the reasons some physicians had for not increasing doses indefinitely were simply a matter of physician "comfort level," which could be overcome or used as a tool to induce them to switch to Actavis's opioid, Kadian.

b. Cephalon sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which claimed that some patients "need" a larger dose of their opioid, regardless of the dose currently prescribed.[85]

c. Cephalon sponsored a CME written by KOL Dr. Lynn Webster, *Optimizing Opioid Treatment for Breakthrough Pain*, which was offered online by Medscape, LLC from September 28, 2007 through December 15, 2008. The CME taught that non- opioid analgesics and combination opioids that include

[85] APF, Treatment Options, https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf.

aspirin and acetaminophen are less effective to treat breakthrough pain because of dose limitations.

d. Cephalon sales representatives assured prescribers that opioids were safe, even at high doses.

e. Endo sponsored a website, painknowledge.com, through APF and NIPC, which, in 2009, claimed that opioids may be increased until "you are on the right dose of medication for your pain," and once that occurred, further dose increases would not occur. Endo funded the site, which was a part of Endo's marketing plan, and tracked visitors to it.

f. Endo distributed a patient education pamphlet edited by KOL Dr. Russell Portenoy titled *Understanding Your Pain: Taking Oral Opioid Analgesics.* In Q&A format, it asked: "If I take the opioid now, will it work later when I really need it?" The response was: "The dose can be increased . . . . You won't 'run out' of pain relief."

g. Janssen sponsored a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which its personnel reviewed and approved an its sales force distributed. This guide listed dose limitations as "disadvantages" of other pain medicines and omitted any discussion of risks of increased doses of opioids. The publication also falsely claimed that it is a "myth" that "opioid doses have to be bigger over time."

h. Purdue's *In the Face of Pain* website, along with initiatives of APF, promoted the notion that if a patient's doctor does not prescribe them what—in their view—is a sufficient dose of opioids, they should find another doctor who will.

In so doing, Purdue exerted undue, unfair, and improper influence over prescribers who face pressure to accede to the resulting demands.

i. Purdue sponsored APF's A Policymaker's Guide to Understanding Pain & Its Management, which taught that dose escalations are "sometimes necessary," even indefinitely high ones. This suggested that high dose opioids are safe and appropriate and did not disclose the risks from high dose opioids. This publication is still available online.[86]

j. Purdue sponsored APF's Treatment Options: A Guide for People Living with Pain (2007), which taught patients that opioids have "no ceiling dose" and are therefore the most appropriate treatment for severe pain. The guide also claimed that some patients "need" a larger dose of the drug, regardless of the dose currently prescribed. [87] This language fails to disclose heightened risks at elevated doses.

k. Purdue sponsored a CME issued by the American Medical Association in 2003, 2007, 2010, and 2013. The CME, Overview of Management Options, was edited by KOL Dr. Russell Portenoy, among others, and taught that other drugs, but not opioids, are unsafe at high doses. The 2013 version is still available for CME credit.

[86] APF, Policymaker's Guide, http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf (last accessed Jul. 12, 2018)
[87] APF, Treatment Options, https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf.

l. Purdue sales representatives told prescribers that opioids were just as effective for treating patients long-term and omitted any discussion that increased tolerance would require increasing, and increasingly dangerous, doses.

231. Once again, the 2016 CDC Guideline reveals that the Manufacturer Defendants' representations regarding opioids were lacking in scientific evidence. The 2016 CDC Guideline clarifies that the "[b]enefits of high-dose opioids for chronic pain are not established" while the "risks for serious harms related to opioid therapy increase at higher opioid dosage."[88] More specifically, the CDC explains that "there is now an established body of scientific evidence showing that overdose risk is increased at higher opioid dosages.[89] The CDC also states that there is an increased risk "for opioid use disorder, respiratory depression, and death at higher dosages.[90] That is why the CDC advises doctors to "avoid increasing dosage" to above 90 morphine milligram equivalents per day.[91]

c. Defendants Minimized Adverse Effects of Opioids and Overstated Risks of Alternatives

232. Each of the following misrepresentations was created with the intent and expectation that, by omitting the known, serious risks of chronic opioid therapy, including the risks of addiction, abuse, overdose, and death, and emphasizing or exaggerating risks of competing products, prescribers and patients would be more likely to choose opioids. Defendants and their third-party allies routinely ignored the risks of chronic opioid therapy. These include (beyond the risks associated with misuse, abuse, and addiction): hyperalgesia, a "known serious risk associated

[88] 2016 CDC Guideline, supra, at 22-23.
[89] *ld.* at 23-24.
[90] *ld.* at 21.
[91] *ld*. at 16.

with chronic opioid analgesic therapy in which the patient becomes more sensitive to certain painful stimuli over time;"[92] hormonal dysfunction; decline in immune function; mental clouding, confusion, and dizziness; increased falls and fractures in the elderly; neonatal abstinence syndrome (when an infant exposed to opioids prenatally withdraws from the drugs after birth); and potentially fatal interactions with alcohol or benzodiazepines, which are used to treat post-traumatic stress disorder and anxiety (disorders frequently coexisting with chronic pain conditions).[93]

233. Despite these serious risks, Defendants asserted, or implied, that opioids were appropriate first-line treatments and safer than alternative treatments, including NSAIDs such as ibuprofen (Advil, Motrin) or naproxen (Aleve). While NSAIDs can pose significant gastrointestinal, renal, and cardiac risks, particularly for elderly patients, Defendants' exaggerated descriptions of those risks were deceptive in themselves, and also made their omissions regarding the risks of opioids all the more striking and misleading. Defendants and their third-party allies described over-the-counter NSAIDs as life-threatening and falsely asserted that they were responsible for 10,000-20,000 deaths annually (more than opioids), when in reality the number is closer to 3,200. This description of NSAIDs starkly contrasted with their representation of opioids, for which the listed risks were nausea,

[92] Letter from Janet Woodcock, M.D., Dir., Ctr. for Drug Eval. & Res., to Andrew Kolodny, M.D., Pres. Physicians for Responsible Opioid Prescribing, Re Docket No. FDA-2012-P-0818 (Sept. 10, 2013).

[93] Several of these risks do appear in the FDA-mandated warnings. *See, e.g.*, the August 13, 2015 OxyContin Label, Section 6.2, identifying adverse reactions including: "abuse, addiction … death, … hyperalgesia, hypogonadism . . . mood altered . . . overdose, palpitations (in the context of withdrawal), seizures, suicidal attempt, suicidal ideation, syndrome of inappropriate antidiuretic hormone secretion, and urticaria [hives]."

constipation, and sleepiness (but not addiction, overdose, or death). Compared with NSAIDs, opioids are responsible for roughly four times as many fatalities annually.

234. As with the preceding misrepresentations, Defendants' false and misleading claims regarding the comparative risks of NSAIDs and opioids had the effect of shifting the balance of opioids' risks and purported benefits. While opioid prescriptions have exploded over the past two decades, the use of NSAIDs has declined during that same time.

235. Each of the following reflects Defendants' deceptive claims and omissions about the risks of opioids, including in comparison to NSAIDs:

a. Documents from a 2010 sales training indicate that Actavis trained its sales force that the ability to escalate doses during long-term opioid therapy, without hitting a dose ceiling, made opioid use safer than other forms of therapy that had defined maximum doses, such as acetaminophen or NSAIDs.

b. Actavis also trained physician-speakers that "maintenance therapy with opioids can be safer than long-term use of other analgesics," including NSAIDs, for older persons.

c. Kadian sales representatives told Charleston County prescribers that NSAIDs were more toxic than opioids.

d. Cephalon sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which taught patients that opioids differ from NSAIDs in that they have "no ceiling dose" and are therefore the most appropriate

treatment for severe pain.[94] The publication attributed 10,000 to 20,000 deaths annually to NSAID overdose. *Treatment Options* also warned that risks of NSAIDs increase if "taken for more than a period of months," with no corresponding warning about opioids.[95]

e. Cephalon sales representatives told County prescribers that NSAIDs were more toxic than Cephalon's opioids.

f. Endo distributed a "case study" to prescribers titled *Case Challenges in Pain Management: Opioid Therapy for Chronic Pain*. The study cites an example, meant to be representative, of a patient "with a massive upper gastrointestinal bleed believed to be related to his protracted use of NSAIDs" (over eight years), and recommends treating with opioids instead.

g. Endo sponsored a website, painknowledge.com, through APF and NIPC, which contained a flyer called *"Pain: Opioid Therapy."* This publication included a list of adverse effects from opioids that omitted significant adverse effects like hyperalgesia, immune and hormone dysfunction, cognitive impairment, tolerance, dependence, addiction, and death. Endo continued to provide funding for this website through 2012, and closely tracked unique visitors to it.

h. Endo provided grants to APF to distribute *Exit Wounds* (2009), which omitted warnings of the risk of interactions between opioids and benzodiazepines,

[94] Am. Pam Found., *Treatment Options: A Guide for People Living in Pain* (2007) [hereinafter APF, Treatment Options], https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf.
[95] *Id*.

which would increase fatality risk. *Exit Wounds* also contained a lengthy discussion of the dangers of using alcohol to treat chronic pain but did not disclose dangers of mixing alcohol and opioids.

i. Endo sales representatives told prescribers that NSAIDs were more toxic than opioids.

j. Janssen sponsored a patient education guide titled *Finding Relief: Pain Management for Older Adults* (2009), which its personnel reviewed and approved and its sales force distributed. This publication described the advantages and disadvantages of NSAIDs on one page, and the "myths/facts" of opioids on the facing page. The disadvantages of NSAIDs are described as involving "stomach upset or bleeding," "kidney or liver damage if taken at high doses or for a long time," "adverse reactions in people with asthma," and "can increase the risk of heart attack and stroke." The only adverse effects of opioids listed are "upset stomach or sleepiness," which the brochure claims will go away, and constipation.

k. Janssen sponsored APF's *Exit Wounds* (2009), which omits warnings of the risk of interactions between opioids and benzodiazepines. Janssen's label for Duragesic, however, states that use with benzodiazepines "may cause respiratory depression, [low blood pressure], and profound sedation or potentially result in coma. *Exit Wounds* also contained a lengthy discussion of the dangers of using alcohol to treat chronic pain but did not disclose dangers of mixing alcohol and opioids.

l. Janssen sales representatives told prescribers that Nucynta was not an opioid, making it a good choice for chronic pain patients who previously were unable to continue opioid therapy due to excessive side effects. This statement was misleading because Nucynta is, in fact, an opioid and has the same effects as other opioids.

m. Purdue sponsored APF's *Exit Wounds* (2009), which omits warnings of the risk of interactions between opioids and benzodiazepines, which would increase fatality risk. *Exit Wounds* also contained a lengthy discussion of the dangers of using alcohol to treat chronic pain but did not disclose dangers of mixing alcohol and opioids.

n. Purdue sponsored APF's Treatment Options: A Guide for People Living with Pain (2007), which advised patients that opioids differ from NSAIDs in that they have "no ceiling dose" and are therefore the most appropriate treatment for severe pain. The publication attributes 10,000 to 20,000 deaths annually to NSAID overdose. Treatment Options also warned that risks of NSAIDs increase if "taken for more than a period of months," with no corresponding warning about opioids.

o. Purdue sponsored a CME issued by the American Medical Association in 2003, 2007, 2010, and 2013; the 2013 version is still available for CME credit. The CME, Overview of Management Options, was edited by KOL Dr. Russell Portenoy, among others, and taught that NSAIDs and other drugs, but not opioids, are unsafe at high doses.

p. Purdue sales representatives told prescribers that NSAIDs were more toxic than opioids.

d. The Manufacturer Defendants made materially deceptive statements and fraudulently concealed material facts/ their misconduct. (MS 130-138)

236. As alleged herein, the Manufacturer Defendants made and/or disseminated deceptive statements regarding material facts and further concealed material facts, in the course of manufacturing, marketing, and selling prescription opioids. The Manufacturer Defendants' actions were intentional and/or unlawful. Such statements include, but are not limited to, those set out below and alleged throughout this Complaint.

237. Defendant Purdue made and/or disseminated deceptive statements, and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

a. Creating, sponsoring, and assisting in the distribution of patient education materials distributed to consumers that contained deceptive statements;

b. Creating and disseminating advertisements that contained deceptive statements concerning the ability of opioids to improve function long-term and concerning the evidence supporting the efficacy of opioids long-term for the treatment of chronic non-cancer pain;

c. Disseminating misleading statements concealing the true risk of addiction and promoting the deceptive concept of pseudoaddiction through Purdue's own unbranded publications and on internet sites Purdue operated that were marketed to and accessible by consumers;

d. Distributing brochures to doctors, patients, and law enforcement officials that included deceptive statements concerning the indicators of possible opioid abuse;

e. Sponsoring, directly distributing, and assisting in the distribution of publications that promoted the deceptive concept of pseudoaddiction, even for high-risk patients;

f. Endorsing, directly distributing, and assisting in the distribution of publications that presented an unbalanced treatment of the long-term and dose dependent risks of opioids versus NSAIDs;

g. Providing significant financial support to pro-opioid KOL doctors who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

h. Providing needed financial support to pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;

i. Assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction;

j. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

k. Developing and disseminating scientific studies that misleadingly concluded opioids are safe and effective for the long-term treatment of chronic noncancer pain and that opioids improve quality of life, while concealing contrary data;

l. Assisting in the dissemination of literature written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic noncancer pain;

m. Creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy;

n. Targeting veterans by sponsoring and disseminating patient education marketing materials that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

o. Targeting the elderly by assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pam and misrepresented the risks of opioid addiction in this population;

p. Exclusively disseminating misleading statements in education materials to hospital doctors and staff while purportedly educating them on new pain standards;

q. Making deceptive statements concerning the use of opioids to treat chronic noncancer pain to prescribers through in-person detailing; and

r. Withholding from law enforcement the names of prescribers Purdue believed to be facilitating the diversion of its opioid, while simultaneously marketing opioids to these doctors by disseminating patient and prescriber education materials and advertisements and CMEs they knew would reach these same prescribers.

238. Defendant Endo made and/or disseminated deceptive statements, and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

a. Creating, sponsoring, and assisting in the distribution of patient education materials that contained deceptive statements;

b. Creating and disseminating advertisements that contained deceptive statements concerning the ability of opioids to improve function long-term and concerning the evidence supporting the efficacy of opioids long-term for the treatment of chronic non-cancer pain;

c. Creating and disseminating paid advertisement supplements in academic journals promoting chronic opioid therapy as safe and effective for long term use for high risk patients;

d. Creating and disseminating advertisements that falsely and inaccurately conveyed the impression that Endo's opioids would provide a reduction in oral, intranasal, or intravenous abuse;

e. Disseminating misleading statements concealing the true risk of addiction and promoting the misleading concept of pseudoaddiction through Endo's own unbranded publications and on internet sites Endo sponsored or operated;

f. Endorsing, directly distributing, and assisting in the distribution of publications that presented an unbalanced treatment of the long-term and dose-dependent risks of opioids versus NSAIDs;

g. Providing significant financial support to pro-opioid KOLs, who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

h. Providing needed financial support to pro-opioid pain organizations -including over $5 million to the organization responsible for many of the most egregious misrepresentations - that made deceptive statements, including in patient

education materials, concerning the use of opioids to treat chronic non-cancer pain;

i. Targeting the elderly by assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction in this population;

j. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

k. Developing and disseminating scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic noncancer pain and that opioids improve quality of life, while concealing contrary data;

l. Directly distributing and assisting in the dissemination of literature written by pro- opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain, including the concept of pseudoaddiction;

m. Creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy; and

n. Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing.

239. Defendant Janssen made and/or disseminated deceptive statements, and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

a. Creating, sponsoring, and assisting in the distribution of patient education materials that contained deceptive statements;

b. Directly disseminating deceptive statements through internet sites over which Janssen exercised final editorial control and approval stating that opioids are safe and effective for the long-term treatment of chronic noncancer pain and that opioids improve quality of life, while concealing contrary data;

c. Disseminating deceptive statements concealing the true risk of addiction and promoting the deceptive concept of pseudoaddiction through internet sites over which Janssen exercised final editorial control and approval;

d. Promoting opioids for the treatment of conditions for which Janssen knew, due to the scientific studies it conducted, that opioids were not efficacious and concealing this information;

e. Sponsoring, directly distributing, and assisting in the dissemination of patient education publications over which Janssen exercised final editorial control and approval, which presented an unbalanced treatment of the long-term and dose dependent risks of opioids versus NSAIDs;

f. Providing significant financial support to pro-opioid KOLs, who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

g. Providing necessary financial support to pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;

h. Targeting the elderly by assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction in this population;

i. Targeting the elderly by sponsoring, directly distributing, and assisting in the dissemination of patient education publications targeting this population that contained deceptive statements about the risks of addiction and the adverse effects of opioids, and made false statements that opioids are safe and effective for the long-term treatment of chronic non-cancer pain and improve quality of life, while concealing contrary data;

j. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

k. Directly distributing and assisting in the dissemination of literature written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain, including the concept of pseudoaddiction;

l. Creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic noncancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy;

m. Targeting veterans by sponsoring and disseminating patient education marketing materials that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain; and

n. Making deceptive statements concerning the use of opioids to treat chronic noncancer pain to prescribers through in-person detailing.

240. Defendant Cephalon made and/or disseminated untrue, false and deceptive statements, and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

a. Creating, sponsoring, and assisting in the distribution of patient education materials that contained deceptive statements;

b. Sponsoring and assisting in the distribution of publications that promoted the deceptive concept of pseudoaddiction, even for high-risk patients;

c. Providing significant financial support to pro-opioid KOL doctors who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain and breakthrough chronic non-cancer pain;

d. Developing and disseminating scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic noncancer pain in conjunction with Cephalon's potent rapid-onset opioids;

e. Providing needed financial support to pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;

f. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

g. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of Cephal on's rapid-onset opioids;

h. Directing its marketing of Cephalon's rapid-onset opioids to a wide range of doctors, including general practitioners, neurologists, sports medicine specialists, and workers' compensation programs, serving chronic pain patients;

i. Making deceptive statements concerning the use of Cephal on's opioids to treat chronic non-cancer pain to prescribers through in-person detailing and speakers' bureau events, when such uses are unapproved and unsafe; and

j. Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing and speakers' bureau events.

241. Defendant Actavis made and/or disseminated deceptive statements, and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

a. Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing;

b. Creating and disseminating advertisements that contained deceptive statements that opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life;

c. Creating and disseminating advertisements that concealed the risk of addiction in the long-term treatment of chronic, non-cancer pain; and

d. Developing and disseminating scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life while concealing contrary data

a. The Manufacturer Defendants, both individually and collectively, made, promoted, and profited from their misrepresentations about the risks and benefits of opioids for chronic pain even though they knew that their misrepresentations were false and deceptive. The history of opioids, as well as research and clinical experience establish that opioids are highly addictive and are responsible for a long list of very serious adverse outcomes. The FDA warned Defendants of this, and Defendants had access to scientific studies, detailed prescription data, and reports of adverse events, including reports of addiction, hospitalization, and death - all of which clearly described the harm from long-term opioid use and that patients were suffering from addiction, overdose, and death in alarming numbers. More recently, the FDA and CDC have issued pronouncements, based on medical evidence, that conclusively expose the falsity of Defendants' misrepresentations, and Endo and Purdue have recently entered agreements in New York prohibiting them from making some of the same misrepresentations described in this Complaint.

b. At all times relevant to this Complaint, the Manufacturer Defendants took steps to avoid detection of and to fraudulently conceal their deceptive marketing and unlawful, unfair, and fraudulent conduct. For example, the Manufacturer Defendants disguised their role in the deceptive marketing of chronic opioid therapy by funding and working through third parties like Front Groups and KOLs. The Manufacturer Defendants purposefully hid behind the assumed credibility of these individuals and organizations and relied on them to vouch for the accuracy and integrity of the Manufacturer Defendants' false and deceptive statements about the risks and benefits of long-term opioid use for chronic pain. Defendants also never disclosed their role in shaping, editing, and approving the content of information and materials disseminated by these third parties. The

Manufacturer Defendants exerted considerable influence on these promotional and "educational" materials in emails, correspondence, and meetings with KOLs, Front Groups, and public relations companies that were not, and have not yet become, public. For example, PainKnowledge.org, which is run by the NIPC, did not disclose Endo's involvement. Other Manufacturer Defendants, such as Purdue and Janssen, ran similar websites that masked their own role.

c. Finally, the Manufacturer Defendants manipulated their promotional materials and the scientific literature to make it appear that these documents were accurate, truthful, and supported by objective evidence when they were not. The Manufacturer Defendants distorted the meaning or import of studies they cited and offered them as evidence for propositions the studies did not support. The Manufacturer Defendants invented "pseudoaddiction" and promoted it to an unsuspecting medical community. The Manufacturer Defendants provided the medical community with false and misleading information about ineffectual strategies to avoid or control opioid addiction. The Manufacturer Defendants recommended to the medical community that dosages be increased, without disclosing the risks. The Manufacturer Defendants spent millions of dollars over a period of years on a misinformation campaign aimed at highlighting opioids' alleged benefits, disguising the risks, and promoting sales.

III. DEFENDANTS BREACHED THEIR DUTY TO PREVENT UNLAWFUL DISTRIBUTION OF OPIOIDS

a. The Distributor Defendants have a duty under federal law to guard against and report unlawful diversion and to report and prevent suspicious orders

242. The Distributor Defendants owe a duty under federal law (21 U.S.C. § 823, 21 CFR 1301.74) to monitor, detect, investigate, refuse to fill, and report suspicious orders of prescription opioids as well as those orders which the Distributor Defendants knew or should have known were likely to be diverted.

243. The foreseeable harm from a breach of these duties is the diversion of prescription opioids for nonmedical purposes.

244. Each Distributor Defendant repeatedly and purposefully breached its duties under state and federal law. Such breaches are a direct and proximate causes of the widespread diversion of prescription opioids for nonmedical purposes.

245. The unlawful diversion of prescription opioids is a direct and proximate cause of the opioid epidemic, prescription opioid abuse, addiction, morbidity and mortality.

246. The Distributor Defendants' intentionally continued their conduct, as alleged herein, with knowledge that such conduct was creating the opioid epidemic and causing the damages alleged herein.

247. Opioids are a controlled substance. These "Schedule II" drugs are controlled substances with a "high potential for abuse." 21 U.S.C. §§ 812(b), 812(2)(A)-(C).

248. Each Distributor Defendant was required to register with the DEA, pursuant to the federal Controlled Substance Act. See 21 U.S.C. § 823(b), (e); 28 C.F.R. § 0.100. Each Distributor Defendant is a "registrant" as a wholesale distributor in the chain of distribution of Schedule II controlled substances with a duty to comply with all security requirements imposed under that statutory scheme.

249. Each Distributor Defendant has an affirmative duty under federal law to act as a gatekeeper guarding against the diversion of the highly addictive, dangerous opioid drugs. Federal law requires that Distributors of Schedule II drugs, including opioids, must maintain "effective control against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels." 21 U.S.C. §§ 823(b)(1).

250. Federal regulations impose a non-delegable duty upon wholesale drug distributors to "design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant [distributor 1 shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." 21 C.F.R. § 1301.74(b).

251. "Suspicious orders" include orders of an unusual Size, orders of unusual frequency or orders deviating substantially from a normal pattern. See 21 CFR 1301.74(b). These criteria are disjunctive and are not all inclusive. For example, if an order deviates substantially from a normal pattern, the size of the order does not matter and the order should be reported as suspicious. Likewise, a wholesale distributor need not wait for a normal pattern to develop over time before determining whether a particular order is suspicious. The size of an order alone, regardless of whether it deviates from a normal pattern, is enough to trigger the wholesale distributor's responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer but also on the patterns of the entirety of the wholesale distributor's customer base and the patterns throughout the relevant segment of the wholesale distributor industry.

252. In addition to reporting all suspicious orders, distributors must also stop shipment on any order which is flagged as suspicious and only ship orders which were flagged as potentially suspicious if, after conducting due diligence, the distributor can determine that the order is not likely to be diverted into illegal channels. S*ee Southwood Pharm., Inc.*, 72 Fed. Reg. 36,487, 36,501 (Drug Enft Admin. July 3, 2007); Masters Pharmaceutical, Inc.

v. Drug Enforcement Administration, No. 15-11355 (D.C. Cir. June 30, 2017). Regardless, all flagged orders must be reported. Id. 150. These prescription drugs are regulated for the purpose of providing a "closed" system intended to reduce the widespread diversion of these drugs out of legitimate channels into the illicit market, while at the same time providing the legitimate drug industry with a unified approach to narcotic and dangerous drug control.[96]

253. Different entities supervise the discrete links in the chain that separate a consumer from a controlled substance. Statutes and regulations define each participant's role and responsibilities.[97]

254. As the DEA advised the Distributor Defendants in a letter to them dated September 27, 2006, wholesale distributors are "one of the key components of the distribution chain. If the closed system is to function properly ... distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes. This responsibility is critical, as ... the illegal

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[96] *See* 1970 U.S.C.C.A.N. 4566, 4571-72.

[97] Brief for Healthcare Distribution Management Association and National Association of Chain Drug Stores as Amici Curiae in Support of Neither Party, *Masters Pharm .• Inc.* v. *U.S. Drug Enft. Admin.* (No. 15-1335) (D.C. Cir. Apr. 4, 2016), 2016 WL 1321983, at *22 [hereinafter Brief for HDMA and NACDS]. The Healthcare Distribution Management Association (HDMA or HMA)--now known as the Healthcare Distribution Alliance (HDA)--is a national, not-for-profit trade association that represents the nation's primary, full-service healthcare distributors whose membership includes, among others: AmerisourceBergen Drug Corporation, Cardinal Health, Inc., and McKesson Corporation. *See generally* HDA, *About*, https://www.healthcaredistribution.org/about (accessed July 12, 2018). The National Association of Chain Drug Stores (NACDS) is a national, not-for-profit trade association that represents traditional drug stores and supermarkets and mass merchants with pharmacies whose membership includes, among others: Walgreen Company, CVS Health, Rite Aid Corporation and Wa1mart. *See generally* NACDS, *Mission*, https://www.nacds.org/about/mission/ (accessed July 12, 2018).

distribution of controlled substances has a substantial and detrimental effect on the health and general welfare of the American people."[98]

255. The Distributor Defendants have admitted that they are responsible for reporting suspicious orders.[99]

256. The DEA sent a letter to each of the Distributor Defendants on September 27, 2006, warning that it would use its authority to revoke and suspend registrations when appropriate. The letter expressly states that a distributor, in addition to reporting suspicious orders, has a "statutory responsibility to exercise due diligence to avoid filling suspicious orders that might be diverted into other than legitimate medical, scientific, and industrial channels."[100] The letter also instructs that "distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes."[101] The DEA warns that "even just one distributor that uses its DEA registration to facilitate diversion can cause enormous harm."

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[98] *See* Letter from Joseph T. Rannazzisi, Deputy Assistant Adm'r, Office of Diversion Control, Drug. Enf't Admin., U.S. Dep't of Justice, to Cardinal Health (Sept. 27, 2006) [hereinafter Rannazzisi Letter] ("This letter is being sent to every commercial entity in the United States registered with the Drug Enforcement Agency (DEA) to distribute controlled substances. The purpose of this letter is to reiterate the responsibilities of controlled substance distributors in view of the prescription drug abuse problem our nation currently faces."), *filed in Cardinal Health, Inc.* v. *Holder*, No. I : 12-cv-00185-RBW (D.D.C. Feb. 10, 2012), ECF No. 14-51.

[99] *See* Brief for HDMA and NACDS, *supra* note 85, 2016 WL 1321983, at *4 ("[R]egulations ... in placefor more than 40 years require distributors to report suspicious orders of controlled substances to DEAbased on information readily available to them (e.g., a pharmacy's placement of unusually frequent or large orders).').

[100] *See* Rannazzisi Letter ("This letter is being sent to every commercial entity in the United States registered with the Drug Enforcement Agency (DEA) to distribute controlled substances. The purpose of this letter is to reiterate the responsibilities of controlled substance distributors in view of the prescription drug abuse problem our nation currently *faces*."),*filed in Cardinal Health, Inc.* v. *Holder*, No. I : 12-cv-00185-RBW (D.D.C. Feb. 10,2012), ECF No. 14-51.

[101] *Id*. at 1.

257. The DEA sent a second letter to each of the Distributor Defendants on December 27, 2007.[102] This letter reminds the Defendants of their statutory and regulatory duties to "maintain effective controls against diversion" and "design and operate a system to disclose to the registrant suspicious orders of controlled substances. "[103] Finally, the DEA letter references the Revocation of Registration issued in *Southwood Pharmaceuticals, Inc.*, 72 Fed. Reg. 36,487-01 (July 3, 2007), which discusses the obligation to report suspicious orders and "some criteria to use when determining whether an order is suspicious."[104]

258. The Distributor Defendants have not only statutory and regulatory responsibilities to detect and prevent diversion of controlled prescription drugs, but undertake such efforts as responsible members of society.

259. The Distributor Defendants knew they were required to monitor, detect, and halt suspicious orders. Industry compliance guidelines established by the Healthcare Distribution Management Association, the trade association of pharmaceutical distributors, explain that distributors are "[a]t the center of a sophisticated supply chain" and therefore "are uniquely situated to perform due diligence in order to help support the security of the controlled substances they deliver to their customers." The guidelines set forth recommended steps in the "due diligence" process, and note in particular: If an order meets or exceeds a distributor's threshold, as defined in the distributor's monitoring

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[102] *Id*. at 2.
[103] *See* Letter from Joseph T. Rannazzisi, Deputy Assistant Adm'r, Office of Diversion Control, Drug. Enrt
Admin., U.S. Dep't of Justice, to Cardinal Health (Dec. 27, 2007), filed in *Cardinal Health, Inc.* v. *Holder*, No. 1:12-cv- 00 185-RBW (D.D.C. Feb. 10,2012) ,ECF No. 14-8.
[104] *Id*.

system, or is otherwise characterized by the distributor as an order of interest, the distributor should not ship to the customer, in fulfillment of that order, any units of the specific drug code product as to which the order met or exceeded a threshold or as to which the order was otherwise characterized as an order of interest.[105]

260. Each of the Distributor Defendants sold prescription opioids, including hydrocodone and/or oxycodone, to retailers from which Defendants knew prescription opioids were likely to be diverted.

261. Each Distributor Defendant owes a duty to monitor and detect suspicious orders of prescription opioids.

262. Each Distributor Defendant owes a duty under federal law to investigate and refuse suspicious orders of prescription opioids.

263. Each Distributor Defendant owes a duty under federal law to report suspicious orders of prescription opioids.

264. Each Distributor Defendant owes a duty under federal law to prevent the diversion of prescription opioids into illicit markets throughout the United States.

265. The foreseeable harm resulting from a breach of these duties is the diversion of prescription opioids for nonmedical purposes and subsequent plague of opioid addiction.

266. The foreseeable harm resulting from the diversion of prescription opioids for nonmedical purposes is abuse, addiction, morbidity and mortality and the damages caused thereby.

b. **Distributor Defendants Breached Their Duties**

[105] Healthcare Distribution Management Association (HDMA) *Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances, filed in Cardinal Health, Inc. v. Holder*, No. 12-5061 (D.C. Cir. Mar. 7, 2012), Doc. No. 1362415 (App'x B).

227. Because distributors handle such large volumes of controlled substances, and are the first major line of defense in the movement of legal pharmaceutical controlled substances from legitimate channels into the illicit market, it is incumbent on distributors to maintain effective controls to prevent diversion of controlled substances. Should a distributor deviate from these checks and balances, the closed system collapses.[106]

228. The sheer volume of prescription opioids distributed to pharmacies in various areas, and/or to pharmacies from which the Distributor Defendants knew the opioids were likely to be diverted, was excessive for the medical need of the community and facially suspicious. Some red flags are so obvious that no one who engages in the legitimate distribution of controlled substances can reasonably claim ignorance of them.[107]

229. The Distributor Defendants failed to report "suspicious orders," or which the Distributor Defendants knew were likely to be diverted, to the federal authorities, including the DEA.

230. The Distributor Defendants unlawfully filled suspicious orders of unusual size, orders deviating substantially from a normal pattern, and/or orders of unusual frequency, and/or in areas from which the Distributor Defendants knew opioids were likely to be diverted.

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[106] *See* Rannazzisi Decl. ¶10, filed in *Cardinal Health, Inc.* v. *Holder,* No. 1:12-cv-00185-RBW (D.D.C. Feb. 10, 2012), ECF No. 14-2.

[107] *Masters Pharmaceuticals, Inc.*, 80 Fed. Reg. 55,418-01, 55,482 (Sept. 15, 2015) (*citing Holiday CVS, L.L.C., d/b/a CVs/Pharmacy Nos.* 219 *and* 5195,77 Fed. Reg. 62,316, 62,322 (2012)).

231. The Distributor Defendants breached their duty to monitor, detect, investigate, refuse and report suspicious orders of prescription opiates, and/or in areas from which the Distributor Defendants knew opioids were likely to be diverted.

232. The Distributor Defendants breached their duty to maintain effective controls against diversion of prescription opiates into other than legitimate medical, scientific, and industrial channels.

233. The Distributor Defendants breached their duty to "design and operate a system to disclose to the registrant suspicious orders of controlled substances" and failed to inform the authorities including the DEA of suspicious orders when discovered, in violation of their duties under federal law.

234. The Distributor Defendants breached their duty to exercise due diligence to avoid filling suspicious orders that might be diverted into channels other than legitimate medical, scientific and industrial channels.[108]

235. The federal laws at issue here are public safety laws.

236. The Distributor Defendants' violations of public safety statutes constitute prima facie evidence of negligence under State law.

237. The unlawful conduct by the Distributor Defendants is purposeful and intentional. The Distributor Defendants refuse to abide by the duties imposed by federal law which are required to legally acquire and maintain a license to distribute prescription opiates.

238. The Distributor Defendants acted with actual malice in breaching their duties, i.e., they have acted with a conscious disregard for the rights and safety of other persons, and said actions have a great probability of causing substantial harm.

[108] *See Cardinal Health, Inc.* v. *Holder*, 846 F. Supp. 2d 203, 206 (D.D.C. 2012).

239. The Distributor Defendants' repeated shipments of suspicious orders, over an extended period of time, in violation of public safety statutes, and without reporting the suspicious orders to the relevant authorities demonstrates wanton, willful, or reckless conduct or criminal indifference to civil obligations affecting the rights of others and justifies an award of punitive damages.

c. **Distributor Defendants Have Sought to Avoid and Have Misrepresented their Compliance with Their Legal Duties.**

240. The Distributor Defendants have repeatedly misrepresented their compliance with their legal duties under federal law and have wrongfully and repeatedly disavowed those duties in an effort to mislead regulators and the public.

241. Wholesale Distributor McKesson has recently been forced to specifically admit to breach of its duties to monitor, report, and prevent suspicious orders. Pursuant to an Administrative Memorandum of Agreement ("2017 Agreement") entered into between McKesson and the DEA in January 2017, McKesson admitted that, at various times during the period from January 1, 2009 through the effective date of the Agreement (January 17, 2017) it "did not identify or report to [the] DEA certain orders placed by certain pharmacies which should have been detected by McKesson as suspicious based on the guidance contained in the DEA Letters."[109] Further, the 2017 Agreement specifically finds that McKesson "distributed controlled substances to pharmacies even though those McKesson Distribution Centers should have known that the pharmacists practicing within those pharmacies had failed to fulfill their corresponding responsibility to ensure that controlled substances were dispensed pursuant to prescriptions issued for

[109] *See* Administrative Memorandum of Agreement between the u.s. Dep't of Justice, the Drug Enf't Admin., and the McKesson Corp. (Jan. 17,2017), https://www.justice.gov/opa/press-release/file/928476/download (accessed July 12, 2018).

legitimate medical purposes by practitioners acting in the usual course of their professional practice, as required by 21 C.F.R § 1306.04(a).”[110] McKesson admitted that, during this time period, it "failed to maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific and industrial channels by sales to certain of its customers in violation of the CSA and the CSA's implementing regulations, 21 C.F.R. Part 1300 et seq., at the McKesson Distribution Centers."

242. The 2017 Memorandum of Agreement followed a 2008 Settlement Agreement in which McKesson also admitted failure to report suspicious orders of controlled substances to the DEA.[111] In the 2008 Settlement Agreement, McKesson "recognized that it had a duty to monitor its sales of all controlled substances and report suspicious orders to DEA," but had failed to do so.[112] The 2017 Memorandum of Agreement documents that McKesson continued to breach its admitted duties by "fail[ing] to properly monitor its sales of controlled substances and/or report suspicious orders to DEA, in accordance with McKesson's obligations.”[113] As a result of these violations, McKesson was fined and required to pay to the United States $150,000,000.[114]

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[110] *Id*. at 4.
[111] *Id*. at 4.
[112] *Id*.
[113] *ld.; see also* Settlement Agreement and Release between the U.S. and McKesson Corp., at 5 (Jan. 17, 2017) [hereinafter 2017 Settlement Agreement and Release] ("McKesson acknowledges that, at various times during the Covered Time Period [2009-2017], it did not identify or report to DBA certain orders placed by certain pharmacies, which should have been detected by McKesson as suspicious, in a manner fully consistent with the requirements set forth in the 2008 MOA."), https://www.justice.gov/opa/press-release/file/928471/download (accessed July 12, 2018).
[114] *See Id*. at 6.

243. Even though McKesson had been sanctioned in 2008 for failure to comply with its legal obligations regarding controlling diversion and reporting suspicious orders, and even though McKesson had specifically agreed in 2008 that it would no longer violate those obligations, McKesson continued to violate the laws in contrast to its written agreement not to do so.

244. Because of the Distributor Defendants' refusal to abide by their legal obligations, the DEA has repeatedly taken administrative action to attempt to force compliance. For example, in May 2014, the United States Department of Justice, Office of the Inspector General, Evaluation and Inspections Divisions, reported that the DEA issued final decisions in 178 registrant actions between 2008 and 2012.[115] The Office of Administrative Law Judges issued a recommended decision in a total of 117 registrant actions before the DEA issued its final decision, including 76 actions involving orders to show cause and 41 actions involving intermediate suspension orders.[116] These actions include the following:

a. On April 24, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the AmerisourceBergen Orlando, Florida distribution center ("Orlando Facility") alleging failure to maintain effective controls against diversion of controlled substances. On June 22,2007, AmerisourceBergen entered into a settlement that resulted in the suspension of its DEA registration;

[115] Evaluation and Inspections Div., Office of the Inspector Gen., U.S. Dep't of Justice, *The Drug Enforcement Administration's Adjudication of Registrant Actions* 6 (2014), https://oig.justice.gov/reports/2014/e1403.pdf (last accessed July 12, 2018)
[116] *Id*.

b. On November 28, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Auburn, Washington Distribution Center ("Auburn Facility") for failure to maintain effective controls against diversion of hydro cod one;

c. On December 5, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Lakeland, Florida Distribution Center ("Lakeland Facility") for failure to maintain effective controls against diversion of hydrocodone;

d. On December 7, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Swedesboro, New Jersey Distribution Center ("Swedesboro Facility") for failure to maintain effective controls against diversion of hydro cod one;

e. On January 30, 2008, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Stafford, Texas Distribution Center ("Stafford Facility") for failure to maintain effective controls against diversion of hydrocodone;

f. On May 2, 2008, McKesson Corporation entered into an Administrative Memorandum of Agreement ("2008 MOA',) with the DEA which provided that McKesson would "maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious orders required by 21 C.F.R. § 1301. 74(b), and follow the procedures established by its Controlled Substance Monitoring Program";

g. On September 30, 2008, Cardinal Health entered into a Settlement and Release Agreement and Administrative Memorandum of Agreement with the DEA related to its Auburn Facility, Lakeland Facility, Swedesboro Facility and Stafford Facility. The document also referenced allegations by the DEA that Cardinal failed to maintain effective controls against the diversion of controlled substances at its distribution facilities located in McDonough, Georgia ("McDonough Facility"), Valencia, California ("Valencia Facility") and Denver, Colorado ("Denver Facility");

h. On February 2, 2012, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Lakeland, Florida Distribution Center ("Lakeland Facility") for failure to maintain effective controls against diversion of oxycodone;

i. On December 23,2016, Cardinal Health agreed to pay a $44 million fine to the DEA to resolve the civil penalty portion of the administrative action taken against its Lakeland, Florida Distribution Center; and

j. On January 5, 2017, McKesson Corporation entered into an Administrative Memorandum Agreement with the DEA wherein it agreed to pay a $150 million civil penalty for violation of the 2008 MOA as well as failure to identify and report suspicious orders at its facilities in Aurora CO, Aurora IL, Delran NJ, LaCrosse WI, Lakeland FL, Landover MD, La Vista NE, Livonia MI, Methuen MA, Sante Fe Springs CA, Washington Courthouse OH and West Sacramento CA.

245. Rather than abide by their non-delegable duties under public safety laws, the Distributor Defendants, individually and collectively through trade groups in the industry, pressured the U.S. Department of Justice to "halt" prosecutions and lobbied Congress to strip the DEA of its ability to immediately suspend distributor registrations. The result was a "sharp drop in enforcement actions" and the passage of the "Ensuring Patient Access and Effective Drug Enforcement Act" which, ironically, raised the burden for the DEA to revoke a distributor's license from "imminent harm" to "immediate harm" and provided the industry the right to "cure" any violations of law before a suspension order can be issued.[117]

246. In addition to taking actions to limit regulatory prosecutions and suspensions, the Distributor Defendants undertook to fraudulently convince the public that they were complying with their legal obligations, including those imposed by licensing regulations. Through such statements, the Distributor Defendants attempted to assure the public they were working to curb the opioid epidemic.

247. For example, a Cardinal Health executive claimed that it uses "advanced analytics" to monitor its supply chain, and represented that it was being "as effective and

[117] Lenny Bernstein & Scott Higham, *Investigation: The DEA Slowed Enforcement While the Opioid Epidemic Grew Out of Control*, Wash. Post, Oct. 22, 2016, https://www.washingtonpost.com/investigations/the-dea-slowed-enforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13-d7c704ef9fd9_story.html?utm_term=.57dd9e32043c (accessed July 13, 2018); Lenny Bernstein & Scott Higham, *Investigation: U.S. Senator Calls for Investigation of DEA Enforcement Slowdown Amid Opioid Crisis*, Wash. Post, Mar. 6, 2017, https://www.washingtonpost.com/investigations/us-senator-calls-for-investigation-of-dea-enforcement-slowdown/2017/03/06/5846ee60-028b-11e7-b1e9-a05d3c21f7cf_story.html?utm_term=.61f36a18c2c9, (accessed July 13, 2018); Eric Eyre, *DEA Agent:"We Had No Leadership" in WV Amid Flood of Pain Pills*, Charleston Gazette-Mail, Feb. IS, 2017, https://www.wvgazettemail.com/news/health/dea-agent-we-had-no-leadership-in-wv-amid-flood/article_928e9bcd-e28e-58b1-8e3f-f08288f539fd.html, (accessed July 13, 2018).

efficient as possible in constantly monitoring, identifying, and eliminating any outside criminal activity."[118] Given the sales volumes and the company's history of violations, this executive was either not telling the truth, or, if Cardinal Health had such a system, it ignored the results.

248. Similarly, Defendant McKesson publicly stated that it has a "best-in-class controlled substance monitoring program to help identify suspicious orders," and claimed it is "deeply passionate about curbing the opioid epidemic in our country."[119] Again, given McKesson's historical conduct, this statement is either false, or the company ignored outputs of the monitoring program.

249. By misleading the public about the effectiveness of their controlled substance monitoring programs, the Distributor Defendants successfully concealed the facts sufficient to arouse suspicion of the claims that the Plaintiff now asserts.

250. Meanwhile, the opioid epidemic rages unabated in the United States.

251. The epidemic still rages because the fines and suspensions imposed by the DEA do not change the conduct of the industry. The distributors, including the Distributor Defendants, pay fines as a cost of doing business in an industry that generates billions of dollars in annual revenue. They hold multiple DEA registration numbers and when one facility is suspended, they simply ship from another facility.

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[118] Lenny Bernstein *et al*., *How Drugs Intended for Patients Ended Up in the Hands of Illegal Users: "No One Was Doing Their Job,"* Wash. Post, Oct. 22, 2016, https://www.washingtonpost.com/investigations/how-drugs-intended-for-patients-ended-up-in-the-hands-of-illegal-users-no-one-was-doing-their-job/2016/10/22/10e79396-30a7-11e6-8ff7-7b6c1998b7a0_story.html?utm_term=.6a8f1d95aeae (accessed July 13, 2018).

[119] Scott Higham *et al*., *Drug Industry Hired Dozens of Officials from the DEA as the Agency Tried to Curb Opioid Abuse*, Wash. Post, Dec. 22, 2016, https://www.washingtonpost.com/investigations/key-officials-switch-sides-from-dea-to-pharmaceutical-industry/2016/12/22/55d2e938-c07b-11e6-b527-949c5893595e_story.html?utm_term=.e3bb235ff695 (accessed July 13, 2018).

252. The wrongful actions and omissions of the Distributor Defendants which have caused the diversion of opioids and which have been a substantial contributing factor to and/or proximate cause of the opioid crisis are alleged in greater detail in Plaintiff's racketeering allegations below.

253. The Distributor Defendants have abandoned their duties imposed under federal law, taken advantage of a lack of DEA law enforcement, and abused the privilege of distributing controlled substances.

d. **The Manufacturer Defendants Have Unlawfully Failed to Prevent Diversion and Monitor, Report and Prevent Suspicious Orders.**

254. The same legal duties to prevent diversion, and to monitor, report, and prevent suspicious orders of prescription opioids that were incumbent upon the Distributor Defendants were also legally required of the Manufacturer Defendants under federal law.

255. Like the Distributor Defendants, the Manufacturer Defendants were required to register with the DEA to manufacture schedule II controlled substances, like prescription opioids. *See* 21 U.S.C. § 823(a). A requirement of such registration is the: maintenance of effective controls against diversion of particular controlled substances and any controlled substance in schedule I or IT compounded there from into other than legitimate medical, scientific, research, or industrial channels, by limiting the importation and bulk manufacture of such controlled substances to a number of establishments which can produce an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate medical, scientific, research, and industrial purposes. 21 USCA § 823(a)(1) (emphasis added).

256. Additionally, as "registrants" under Section 823, the Manufacturer Defendants were also required to monitor, report, and prevent suspicious orders of controlled

substances: The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency. 21 C.F.R. § 1301.74. See also 21 C.F.R. § 1301.02 ("Any term used in this part shall have the definition set forth in section 102 of the Act (21 U.S.C. 802) or part 1300 of this chapter."); 21 C.F.R. § 1300.01 ("Registrant means any person who is registered pursuant to either section 303 or section 1008 of the Act (21 U.S.C. 823 or 958)." Like the Distributor Defendants, the Manufacture Defendants breached these duties.

257. The Manufacturer Defendants had access to and possession of the information necessary to monitor, report, and prevent suspicious orders and to prevent diversion. The Manufacturer Defendants engaged in the practice of paying "chargebacks" to opioid distributors. A chargeback is a payment made by a manufacturer to a distributor after the distributor sells the manufacturer's product at a price below a specified rate. After a distributor sells a manufacturer's product to a pharmacy, for example, the distributor requests a chargeback from the manufacturer and, in exchange for the payment, the distributor identifies to the manufacturer the product, volume and the pharmacy to which it sold the product. Thus, the Manufacturer Defendants knew - just as the Distributor Defendants knew - the volume, frequency, and pattern of opioid orders being placed and filled. The Manufacturer Defendants built receipt of this information into the payment structure for the opioids provided to the opioid distributors.

258. Federal statutes and regulations are clear: just like opioid distributors, opioid manufacturers are required to "design and operate a system to disclose ... suspicious orders of controlled substances" and to maintain "effective controls against diversion." 21 C.F.R. § 1301.74; 21 USCA § 823(a)(I).

259. The Department of Justice has recently confirmed the suspicious order obligations clearly imposed by federal law upon opioid manufacturers, fining Mallinckrodt $35 million for failure to report suspicious orders of controlled substances, including opioids, and for violating record keeping requirements.[120]

260. In the press release accompanying the settlement, the Department of Justice stated: Mallinckrodt did not meet its obligations to detect and notify DEA of suspicious orders of controlled substances such as oxycodone, the abuse of which is part of the current opioid epidemic. These suspicious order monitoring requirements exist to prevent excessive sales of controlled substances, like oxycodone .... Mallinckrodt's actions and omissions formed a link in the chain of supply that resulted in millions of oxycodone pills being sold on the street. ... "Manufacturers and distributors have a crucial responsibility to ensure that controlled substances do not get into the wrong hands .... "[121]

261. Among the allegations resolved by the settlement, the government alleged "Mallinckrodt failed to design and implement an effective system to detect and report 'suspicious orders' for controlled substances - orders that are unusual in their frequency, size, or other patterns . . . [and] Mallinckrodt supplied distributors, and the distributors

[120] *See* Press Release, U.S. Dep't of Justice, Mallinckrodt Agrees to Pay Record $35 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs and for Recordkeeping Violations(July 11, 2017), https://www.justice.gov/opa/pr/mallinckrodt-agrees-pay-record-35-million-settlement-failure-report-suspicious-orders (accessed July 12, 2018).
[121] *Id*.

then supplied various U.S.. pharmacies and pain clinics, an increasingly excessive quantity of oxycodone pills without notifying DEA of these suspicious orders."[122]

262. The Memorandum of Agreement entered into by Mallinckrodt ("2017 Mallinckrodt MOA") avers "[a]s a registrant under the CSA, Mallinckrodt had a responsibility to maintain effective controls against diversion, including a requirement that it review and monitor these sales and report suspicious orders to DEA."[123]

263. The 2017 Mallinckrodt MOA further details the DEA's allegations regarding Mallinckrodt's failures to fulfill its legal duties as an opioid manufacturer: With respect to its distribution of oxycodone and hydrocodone products, Mallinckrodt's alleged failure to distribute these controlled substances in a manner authorized by its registration and Mallinckrodt's alleged failure to operate an effective suspicious order monitoring system and to report suspicious orders to the DEA when discovered as required by and in violation of 21 C,F .R. § 1301.74(b). The above includes, but is not limited to Mallinckrodt's alleged failure to:

a. Conduct adequate due diligence of its customers;
b. Detect and report to the DEA orders of unusual size and frequency;
c. Detect and report to the DEA orders deviating substantially from normal patterns including, but not limited to, those identified in letters from the DEA Deputy Assistant Administrator, Office of Diversion Control, to registrants dated September 27,2006 and December 27, 2007:
    i. orders that resulted in a disproportionate amount of a substance which is most often abused going to a particular geographic region where there was known diversion,
    ii. orders that purchased a disproportionate amount of substance which is most often abused compared to other products, and

[122] *Id*.
[123] Administrative Memorandum of Agreement between the United States Department of Justice, the Drug Enforcement Agency, and Mallinckrodt, pic. and its subsidiary Mallinckrodt, LLC (July 10, 2017), https://www.justice.gov/usao-edmi/press-release/file/986026/download. ("2017 Mallinckrodt (accessed July 12, 2018) MOA").

iii. orders from downstream customers to distributors who were purchasing from multiple different distributors, of which Mallinckrodt was aware;

d. Use "chargeback" information from its distributors to evaluate suspicious orders. Chargebacks include downstream purchasing information tied to certain discounts, providing Mallinckrodt with data on buying patterns for Mallinckrodt products; and

e. Take sufficient action to prevent recurrence of diversion by downstream customers after receiving concrete information of diversion of Mallinckrodt product by those downstream customers.[124]

264. Mallinckrodt agreed that its "system to monitor and detect suspicious orders did not meet the standards outlined in letters from the DEA Deputy Administrator, Office of Diversion Control, to registrants dated September 27, 2006 and December 27, 2007." Mallinckrodt further agreed that it "recognizes the importance of the prevention of diversion of the controlled substances they manufacture" and would "design and operate a system that meets the requirements of 21 CFR 1301.74(b) ... [such that it would] utilize all available transaction information to identify suspicious orders of any Mallinckrodt product. Further, Mallinckrodt agrees to notify DEA of any diversion and/or suspicious circumstances involving any Mallinckrodt controlled substances that Mallinckrodt discovers."[125]

265. Mallinckrodt acknowledged that "[a]s part of their business model Mallinckrodt collects transaction information, referred to as chargeback data, from their direct customers (distributors). The transaction information contains data relating to the direct customer sales of controlled substances to "downstream" registrants." Mallinckrodt agreed that, from this data, it would "report to the DEA when Mallinckrodt concludes that

[124] 2017 Mallinckrodt MOA at p. 2-3.
[125] *Id*. at 3-4.

the chargeback data or other information indicates that a downstream registrant poses a risk of diversion."[126]

266. The same duties imposed by federal law on Mallinckrodt were imposed upon all Manufacturer Defendants.

267. The same business practices utilized by Mallinckrodt regarding "charge backs" and receipt and review of data from opioid distributors regarding orders of opioids were utilized industry-wide among opioid manufacturers and distributors, including, upon information and belief, the other Manufacturer Defendants.

268. Through, *inter alia*, the charge back data, the Manufacturer Defendants could monitor suspicious orders of opioids.

269. The Manufacturer Defendants failed to monitor, report, and halt suspicious orders of opioids as required by federal law.

270. The Manufacturer Defendants' failures to monitor, report, and halt suspicious orders of opioids were intentional and unlawful.

271. The Manufacturer Defendants have misrepresented their compliance with federal law.

272. The wrongful actions and omissions of the Manufacturer Defendants which have caused the diversion of opioids and which have been a substantial contributing factor to and/or proximate cause of the opioid crisis are alleged in greater detail in Plaintiff's racketeering allegations below.

273. The Manufacturer Defendants' actions and omissions in failing to effective prevent diversion and failing to monitor, report, and prevent suspicious orders have

[126] *Id*. at 5.

enabled the unlawful diversion of opioids throughout the United States and South Carolina.

f. Defendant Insys actively participated in the diversion of opioids.

274. Insys was co-founded in 2002 by Dr. John Kapoor, a serial pharmaceutical industry entrepreneur "known for applying aggressive marketing tactics and sharp price increases on older drugs."[127]

275. In 2012, Insys received U.S. Food and Drug Administration approval for Subsys, a fentanyl sublingual spray product designed to treat breakthrough cancer pain. However, Insys encountered significant obstacles due to insurers employing a process known as prior authorization. Prior authorization prevents the over prescription and abuse of powerful and expensive drugs. The prior authorization process requires "additional approval from an insurer or its pharmacy benefit manager before dispensing…" and may also impose step therapy which requires beneficiaries to first use less expensive medications before moving on to a more expensive approach.[128]

276. Insys circumvented this process by forming a prior authorization unit, known at one point as the Insys Reimbursement Center ("IRC"), to facilitate the process using aggressive and likely illegal marketing techniques. Insys published education articles that praised their products' non-addictive nature; and funded patient advocacy groups who

[127] U.S. senate Homeland Security & Governmental Affairs Committee, Insys Therapeutics and the Systemic Manipulation of Prior Authorization (quoting Fentanyl Billionaire Comes Under Fire as Death Toll Mounts From Prescription Opioids, Wall Street Journal) (Nov. 22, 2016) (www.wsj.com/articles/fentanylbillionaire- comes-under-fire-as-death-toll-mounts-from-prescription-opioids-1479830968) (accessed July 13, 2018).

[128] Senate Permanent Subcommittee on Investigations, Combatting the Opioid Epidemic: A Review of Anti- Abuse Efforts in Medicare and Private Health Insurance Systems; see also Department of Health and Human Services, Centers for Medicare & Medicaid Services, How Medicare Prescription Drug Plans & Medicare Advantage Plans with Prescription Drug Coverage Use Pharmacies, Formularies, & Common Coverage Rules

unknowingly promoted Insys' agenda of raising the profile of pain so that drugs could be prescribed to treat it. Furthermore, Insys' former sales representatives, motivated by corporate greed, paid off medical practitioners to prescribe Subsys in spite of any medical need.[129] Insys employees were pressured internally and received significant monetary incentives to increase the rate of prescription approvals.[130]

277. According to a federal indictment and ongoing congressional investigation by Sen. Claire McCaskill, IRC employees pretended to be with doctors' offices and falsified medical histories of patients. The report, acquired by McCaskill's investigators, includes transcripts and an audio recording of employees implementing these techniques in order to obtain authorization from insurers and pharmacy benefit managers. The transcript reveals an Insys employee pretending to call on behalf of a doctor and inaccurately describes the patient's medical history.[131] For example, Insys employees would create the impression that the patient had cancer, without explicitly saying so, because cancer was a requirement for prior clearance to prescribe Subsys. Insys was warned by a consultant that it lacked needed policies for governing such activities, but the executives failed to implement corrective internal procedures.

[129] Lopez, Linette. "It's been a brutal week for the most shameless company in the opioid crisis-and it's about to get worse," Business Insider, https://nordic.businessinsider.com/opioid-addiction-drugmaker-insys-arrests-justice-department-action-2017- 7/ (accessed July 16, 2018)
[130] Boyd, Roddy. Murder Incorporated: Insys Therapeutics. Part 1. Southern Investigative Reporting Foundation. http://sirf-online.org/2015/12/03/murder-incorporated-the-insys-therapeutics-story/ (accessed July 16, 2018); *see also* Indictment. *United States v. Babich, et al.*, D. Mass. (No. 1;16 CR 10343).
[131] U.S. Senate Homeland Security & Governmental Affairs Committee, Fueling an Epidemic: Insys Therapeutics and the Systematic Manipulation of Prior Authorization, see p. 7-10, available at https://www.documentcloud.org/documents/3987564-REPORT-Fueling-an-Epidemic-Insys-Therapeutics.html (accessed July 16, 2018)

278. In a class action law suit against Insys, it was revealed that management "was aware that only about 10% of prescriptions approved through the Prior Authorization Department were for cancer patients," and an Oregon Department of Justice Investigation found that 78% of preauthorization forms submitted by Insys on behalf of Oregon patients were for off-label uses.[132] Physicians are allowed to prescribe medications for indications outside of FDA guidelines if they see fit, but it is illegal for pharmaceutical companies to market a drug for off-label use.

279. In 2008, biopharmaceutical company Cephalon settled with the U.S. Government for425 million in a suit against the company that alleged it marketed drugs for unapproved uses (off-label). The FDA approved the drug only for opioid tolerant cancer patients. According the Oregon settlement and class-action lawsuit, at least three employees involved in sales and/or marketing at Cephalon had moved over to Insys Therapeutics.[133]

280. Additionally, Insys created a "legal speaker program" which turned out to be a scam. The Justice Department commented on the program and stated:

> The Speaker Programs, which were typically held at high-end restaurants, were ostensibly designed to gather licensed healthcare professionals who had the capacity to prescribe Subsys and educate them about the drug. In truth, the events were usually just a gathering of friends and co-workers, most of whom did not have the ability to prescribe Subsys, and no educational component took place. "Speakers" were paid a fee that ranged from $1,000 to several thousand dollars for attending these dinners. At times, the sign-in sheets for the Speaker Programs were forged so as to make it appear that the programs had an appropriate audience of healthcare professionals.

[132] Gusovsky, Dina. The Pain Killer: A drug Company Putting Profits Above Patients, CNBC (https://www.cnbc.com/2015/11/04/the-deadly-drug-appeal-of-insys-pharmaceuticals.html) (accessed July 16, 2018).
[133] *Id*.

281. Insys paid hundreds of thousands of dollars to doctors in exchange for prescribing Subsys and three top prescribers have already been convicted of taking bribes.

282. Fentanyl products are considered to be the most potent and dangerous opioids on the market and up to 50 times more powerful than heroine.[134]

283. In an internal presentation dated 2012 and entitles, "2013 SUBSYS Brand Plan," Insys identified one of six "key strategic imperatives" as "Mitigate Prior Authorization barriers."[135] On a later slide, the company identified several tasks associated with this effort, including "Build internal [prior authorization] assistance infrastructure," "Establish an internal 1-800 reimbursement assistance hotline," and "Educate field force on [prior authorization] process and facilitation."[136]

284. Additional materials produced by Insys to the minority staff suggest, however, that Insys did not match these efforts with sufficient compliance processes to prevent fraud and was internally aware of the danger of problematic practices. Specifically, on February 18, 2014, Compliance Implementation Services (CIS)—a healthcare consultant—issued a draft report to Insys titled, "Insys Call Note,

[134] U.S. Department of Justice. Drug Enforcement Administration. A Real Threat to Law Enforcement: Fentanyl. https://www.dea.gov/druginfo/DEA%20Targets%20Fentanyl%20%20A%20Real%20Threat%20to%20Law%20Enforcement%20(2016).pdf

[135] U.S. senate Homeland Security & Governmental Affairs Committee, Insys Therapeutics and the Systemic Manipulation of Prior Authorization (quoting Insys Therapeutics, Inc., 2013 Subsys Brand Plan, 2012 Assessment (2012) (INSYS_HSGAC_00007472)). Available at https://www.hsgac.senate.gov/imo/media/doc/REPORT%20-%20Fueling%20an%20Epidemic%20-%20Insys%20Therapeutics%20and%20the%20Systemic%20Manipulation%20of%20Prior%20Authorization.pdf

[136] *Id*. at INSYS_HSGAC_00007765.

Email, & IRC Verbatim Data Audit Report."[137] The introduction to the report explained that "CIS was approached by INSYS' legal representative … on behalf of the Board of Directors for Insys to request that CIS support in review of certain communications with Health Care Professionals (HCPs) and INSYS employees, and report how there were being documented."[138] Insys had expressed concerns "with respect to communications with HCPs by INSYS employees being professional in nature and in alignment with INSYS approved topics regarding off or on-label promotion of an INSYS product, and general adherence to INSYS documentation requirements."[139] An additional concern "stemmed from the lack of monitoring of commercial activities where these types of interactions could occur."[140]

285. Given these issues, Insys requested that CIS review—in part—"the general communications from the INSYS Reimbursement Center (IRC) to HCPs, their office staff or representatives, as well as health insurance carriers … to ensure they were appropriate in nature with respect to specific uses of SUBSYS, INSYS' commercially marketed product."[141]

286. According to the findings CIS issued, Insys lacked formal policies governing the actions of its prior authorization unit. For example, "[n]o formal and approved policy on appropriate communications between IRC employees and HCPs, their staff,

[137] *Id*. (quoting Compliance Implementation Services, Insys Call Note, Email & IRC Verbatim Data Audit Report (Feb. 18, 2014) (INSYS_HSGAC_00007763)).
[138] *Id*.(citing INSYS_HSGAC_00007765).
[139] *Id*.
[140] *Id*.
[141] *Id*.

[health care insurers (HCIs)], or patients exists…that governs the support function of obtaining a prior authorization for the use of SUBSYS."[142]

287. In addition, the report noted that "there were also gaps in formally approved foundational policies, procedures, and [standard operating procedures] with respect to required processes specifically within the IRC."[143]

288. In fact, "[t]he majority of managerial directives, changes to controlled documents or templates, as well as updates or revisions to processes were not formally approved, documented, and disseminated for use, and were sent informally via email blast."[144]

289. Although four informal standard operating procedures existed with regarded to IRC functions, these documents "lacked a formal review and approval" and failed to "outline appropriately the actions performed within the IRC."[145]

290. The report also explains that Insys lacked procedures for auditing interactions between IRC employees and outside entities. According to CIS, "no formal, documented, or detailed processes by which IRC representatives' calls via telephone were audited for proper communication with HCPs or HCIs in any fashion [existed] other than random physical review of a call in a very informal and sporadic manner."[146]

[142] *Id*. (citing INSYS_HSGAC_00007770).
[143] *Id*. (citing INSYS_HSGAC_00007768).
[144] *Id*. (citing INSYS_HSGAC_00007771).
[145] *Id*. (citing INSYS_HSGAC_00007770).
[146] *Id*. (citing INSYS_HSGAC_00007769).

291. More broadly, the report notes that "no formal and documented auditing and monitoring or quality control policy, process, or function exists between IRC employee communications and HCPs, HCP staff, HCIs, or patients."[147]

292. At the end of the report, CIS provided a number of recommendations concerning IRC activities. First, CIS suggested that IRC management "formally draft and obtain proper review and approval of an IRC specific policy detailing the appropriate communications that should occur while performing the IRC associate job functions and interacting with HCPs."[148]

293. Similarly, IRC management was urged to formally draft IRC-specific standard operating procedures "specific to each job function within the IRC," accompanied by "adequate training and understanding of these processes."[149] To ensure compliance with IRC standards, Insys was also directed to create an electronic system to allow management "to monitor both live and anonymously IRC employee communications both incoming and outgoing."[150] Finally, CIS recommended that Insys institute a formal process for revising and updating "IRC documentation used for patient and HCP data."[151]

294. The CIS report concluded by noting, in part, that a review of ten conversations between IRC employees and healthcare providers, office staff, and insurance carriers

[147] *Id*. (citing INSYS_HSGAC_00007771).
[148] *Id*. (citing INSYS_HSGAC_00007770).
[149] *Id*. (citing INSYS_HSGAC_00007771).
[150] *Id*.
[151] *Id*.

revealed "that all IRC staff was professional in communication, and in no instance was inaccurate or off-label usage of SUBSYS communicated."[152]

295. Yet within a year of this conclusion, according to the recording transcribed below, an Insys IRC employee appears to have misled a PBM representative regarding the IRC employee's affiliation and the diagnosis applicable to Sarah Fuller. The alleged result, in that case, was death due to inappropriate and excessive Subsys prescriptions.

296. One former Insys sales representative described the motto of this approach to patients as "Start them high and hope they don't die."[153]

297. Insys failed to monitor, report, and halt suspicious orders of opioids as required by federal law.

298. Insys's failures to monitor, report, and halt suspicious orders of opioids were intentional and unlawful.

299. Insys has misrepresented their compliance with federal law.

300. The wrongful actions and omissions of Insys, which have caused the diversion of opioids and which have been a substantial contributing factor to and/or proximate cause of the opioid crisis harming Plaintiff and the Class.

301. Insys's actions and omissions in failing to effective prevent diversion and failing to monitor, report, and prevent suspicious orders have enabled the unlawful diversion of opioids throughout the United States and South Carolina.

IV. DEFENDANTS CAUSED HARM TO THE NAMED PLAINTIFF AND CLASS

302. Plaintiff and the Class members have treated, and continue to treat, numerous patients for opioid-related conditions, specifically, opioid overdose.

[152] *Id*. (citing INSYS_HSGAC_00007772).
[153] Amended Class Action Complaint, *Larson v. Insys Therapeutics Inc*. (D. Ariz. Oct. 27, 2014.)

303. Additionally, opioid users present themselves to Plaintiff and the Class members claiming to have illnesses and medical problems, which are actually pretexts for obtaining opioids to satisfy their cravings. Plaintiff and the Class members incur operational costs, consisting of expending time and incurring expenses, in diagnosing, testing, and otherwise dealing with these "pill seekers" before their true status can be determined and they can be rejected as patients.

304. Plaintiff and the Class members are required by law to treat emergency cases, including those as the result of opioid use.

305. Average charges for opioid overdose patients treated and released from the emergency department are $3,397 per visit.[154]

306. In 2016, there were 42,249 opioid overdose deaths in the United States, more than quadruple the number in 2001.[155]

307. Research suggests that visits to emergency rooms for suspected opioid overdoses rose 30% in the United States from July 2016 to September 2017 across 45 states, and 35% across 16 states.[156]

308. Collectively, the patients described above will be referred to herein as "patients with opioid conditions."

309. These patients' opioid conditions are the direct and proximate result of the opioid epidemic created and engineered by Defendants.

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[154] https://www.americanprogress.org/issues/healthcare/news/2017/06/20/434708/senates-opioid-fund-cannot-substitute-health-coverage/ (last accessed July 12, 2018)

[155] https://www.kff.org/medicaid/issue-brief/the-opioid-epidemic-and-medicaids-role-in-facilitating-access-to-treatment/) (last accessed July 12, 2018)

[156]https://www.pharmacytimes.com/news/cdc-emergency-department-data-signal-worsening-opioid-epidemic-, (accessed July 12, 2018)

310. Nationwide, 2.66 million people had OUD as of 2015. Of these, 1.37 million have incomes below 200 percent of the federal poverty level.[157]

311. The number of people treated for opioid use conditions who have incomes below 200 percent of the federal poverty level is 343,000 in 2015 and estimated to reach 1.1 million in 2026.[158]

312. Plaintiff and the Class members each have a price list, which sets the prices for a comprehensive listing of items billable to an emergency visit patient or the patient's health insurance provider.

313. These are the full charges for the emergency room physicians' services. The full charges are only partially reimbursed by private health insurers, Medicare, and Medicaid. Plaintiff and the Class members have provider agreements with private health insurers whereby they accept payment from the health insurers at a discounted rate on behalf of insured patients. The difference between the full charges and the discounted rate is lost to the hospitals. Medicare and Medicaid bill emergency room physicians at set rates that are less than the emergency room physicians' full charges, and the difference between the set rates and the full charges is lost to the emergency room physicians.

314. Plaintiff and the Class members bill their full charges to uninsured patients. Typically, where there is no health insurance, Medicare, or Medicaid coverage, these charges are not reimbursed and are lost to emergency room physicians.

315. Plaintiff and the Class members incur partial monetary losses for patients with health insurance, and total monetary losses for uninsured patients, in the treatment of

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157 https://www.americanprogress.org/issues/healthcare/news/2017/06/20/434708/senates-opioid-fund-cannot-substitute-health-coverage/ (accessed July 12, 2018)

158 *Id.*

patients with opioid conditions. These patients would not have presented to Plaintiff and the Class members, and would not have had opioid conditions, but for the opioid epidemic created and engineered by Defendants. Accordingly, Plaintiff's and the Class members' aforesaid monetary losses are the direct and proximate result of Defendants' acts and omissions previously specified herein.

316. Uninsured adults were more likely than those with private health insurance or a public health plan to visit the emergency room due to having no other place to go.[159]

317. Defendants' marketing of opioids caused Plaintiff and the putative class he seeks to represent to diagnose, care for and treat opioid addicted patients who presented with opioid addicted symptoms. All of these medical services provided by Plaintiff were caused by Defendants' fraudulent marketing and scheme. Defendants should be held responsible for all economic damages suffered by Plaintiff and the putative class he seeks to represent. Plaintiff is obligated to cover medically necessary and reasonably required care; he had no choice but to provide these services although often he was not paid or was paid substantially less than market rates.

318. The fact that Plaintiff and the class he seeks to represent would have to provide medical services for opioid addicted patients was both the foreseeable and intended consequence of Defendants' fraudulent marketing scheme. Defendants set out to change the medical and general consensus supporting chronic opioid therapy with the intention of encouraging doctors to prescribe, long- term prescriptions of opioids to treat chronic pain despite the absence of genuine evidence supporting chronic opioid therapy and the

[159] https://www.cdc.gov/nchs/data/nhis/earlyrelease/emergency_room_use_january-june_2011.pdf (accessed July 12, 2018).

contrary evidence regarding the significant risks and limited benefits from long-term use of opioids.

319. Because opioids are very dangerous and highly addictive drugs, it was foreseeable to Defendants that the opioid epidemic would result in a corresponding epidemic of patients with opioid conditions in emergency rooms. It was also foreseeable to Defendants that Plaintiff and the Class members would suffer the aforesaid monetary losses because of the opioid epidemic, since emergency room physicians typically are not reimbursed for their treatment of uninsured patients and receive only partial reimbursement for their treatment of patients with health insurance.

320. Defendants' misrepresentations were material to, and influenced, the opioid-addicted patients presented to Plaintiff and the class he seeks to represent. In the first instance, Plaintiff would not have been presented with, or required to diagnose, care and treat these opioid-addicted patients, but for Defendants' fraudulent and deceptive marketing. Second, Plaintiff has demonstrated that Defendants' marketing is material by setting forth in detail Defendants' wrongful acts.

321. Death statistics represent only the tip of the iceberg. According to 2009 data, for every overdose death that year, there were nine abuse treatment admissions, 30 emergency department visits for opioid abuse or misuse, 118 people with abuse or addiction problems, and 795 non-medical users. Nationally, there were more than 488,000 emergency room admissions for opioids other than heroin in 2008 (up from almost 173,000 in 2004).

322. Emergency room visits tied to opioid use likewise have sharply increased in throughout the country.

323. Emergency rooms are charged with great opportunity to address this opioid epidemic with proper support. Debra Houry, MD, MPH, Director of the National Center for Injury Prevention and Control at the CDC, emphasized that " EDs are a critical entry point for prevention of overdose , with opportunities to improve opioid prescribing, respond to overdoses with overdose education and naloxone distribution, engage in motivational interviewing of patients, initiate treatment for opioid use disorder, and improve surveillance efforts in collaboration with health departments. EDs and physicians who engage in these efforts can save patient lives and reduce health care costs."[160]

RICO ALLEGATIONS

I. The Opioid Diversion Enterprise

324. Recognizing that there is a need for greater scrutiny over controlled substances due to their potential for abuse and danger to public health and safety, the United States Congress enacted the Controlled Substances Act in 1970.[161] The CSA and its implementing regulations created a closed-system of distribution for all controlled substances and listed chemicals.[162] Congress specifically designed the closed chain of distribution to prevent the diversion of legally produced controlled substances into the illicit market.[163] As reflected in comments from United States Senators during deliberation on the CSA, the "[CSA] is designed to crack down hard on the narcotics pusher and the illegal diverters of pep pills

[160] https://www.forbes.com/sites/robertglatter/2018/03/15/how-er-doctors-are-fighting-the-opioid-crisis/#5a0ef27554fd (accessed July 12, 2018).
[161] Joseph T. Rannazzisi Decl. ¶ 4, *Cardinal Health, Inc. v. Eric Holder, Jr., Attorney Genera*l, D.D.C. Case No. 12- cv-185 (Document 14-2 February 10, 2012).
[162] *See* H.R. Rep. No. 91-1444, 1970 U.S.C.C.A.N. at 4566.
[163] *Gonzalez v. Raich*, 545 U.S. 1, 12-14 (2005); 21 U.S.C. § 801(20; 21 U.S.C. §§ 821-824, 827, 880; H.R. Rep. No. 91-1444, 1970 U.S.C.C.A.N. 4566, 4572 (Sept. 10, 1970).

and goof balls."[164] Congress was concerned with the diversion of drugs out of legitimate channels of distribution when it enacted the CSA and acted to halt the "widespread diversion of [controlled substances lout of legitimate channels into the illegal market."[165] Moreover, the closed-system was specifically designed to ensure that there are multiple ways of identifying and preventing diversion through active participation by registrants within the drug delivery chain.[166] All registrants -- manufacturers and distributors alike -- must adhere to the specific security, recordkeeping, monitoring and reporting requirements that are designed to identify or prevent diversion.[167] When registrants at any level fail to fulfill their obligations, the necessary checks and balances collapse.[168] The result is the scourge of addiction that has occurred.

325. In 2006 and 2007, the DEA issued multiple letters to the Distributor Defendants reminding them of their obligation to maintain effective controls against diversion of particular controlled substances, design and operate a system to disclose suspicious orders, and to inform the DEA of any suspicious orders.[169] The DEA also published suggested

[164] *See* H.R Rep. No. 91-1444, 1970 U.S.C.C.A.N. at 4566; 116 Congo Rec. 977-78 (Comments of Sen. Dodd, Jan 23, 1970).
[165] *See* Testimony of Joseph T. Rannazzisi before the Caucus on International Narcotics Control, United State Senate, May 5, 2015 (available at https://www.drugcaucus.senate.gov/sites/default/files/Rannazzisi%20Testimony_0.pdf).
[166] *See* Statement of Joseph T. Rannazzisi before the Caucus on International Narcotics Control United States Senate, July 18, 2012 (available at https://www.dea.gov/pr/speeches-testimony/2012-2009/responding-to-prescription-drug-abuse.PDF).
[167] *Id*.
[168] Joseph T. Rannazzisi Decl. ¶10, *Cardinal Health, Inc. V. Eric Holder, Jr., Attorney General*, D.D.C. Case No. 12-cv-185 (Document 14-2 February 2012).
[169] Joseph T. Rannazzisi, In Reference to Registration # RC0183080 (September 27.2006); Joseph T. Rannazzisi, In Reference to Registration # RC0183080 (December 27, 2007).

questions that a distributor should ask prior to shipping controlled substances, in order to "know their customers."[170]

326. Central to the closed-system created by the CSA was the directive that the DEA determine quotas of each basic class of Schedule I and II controlled substances each year. The quota system was intended to reduce or eliminate diversion from "legitimate channels of trade" by controlling the "quantities of the basic ingredients needed for the manufacture of [controlled substances], and the requirement of order forms for all transfers of these drugs."[171] When evaluating production quotas, the DEA was instructed to consider the following information:

a. Information provided by the Department of Health and Human Services;

b. Total net disposal of the basic class by all manufacturers;

c. Trends in the national rate of disposal of the basic class;

d. An applicant's production cycle and current inventory position;

e. Total actual or estimated inventories of the class and of all substances manufactured from the class and trends in inventory accumulation; and

f. Other factors such as: changes in the currently accepted medical use of substances manufactured for a basic class; the economic and physical availability of raw

[170] Suggested Questions a Distributor should ask prior to shipping controlled substances, Drug Enforcement Administration (available at https://www.deadiversion.usdoj.gov/mtgs/pharm_industry/14th_pharm/levinl_ques.pdf) (accessed July 13, 2018).

[171] 1970 U.S.C.C.A.N. 4566 at 5490; see also Testimony of Joseph T. Rannazzisi before the Caucus on International Narcotics Control, United States Senate, May 5, 2015 (available at https://www.drugcaucus.senate.gov/sites/default/files/Rannazzisi%20Testimony_0.pdf) (accessed July 13, 2018).

materials; yield and sustainability issues; potential disruptions to production; and unforeseen emergencies.[172]

327. It is unlawful for a registrant to manufacture a controlled substance in Schedule II, like prescription opioids, that is (1) not expressly authorized by its registration and by a quota assigned to it by DEA, or (2) in excess of a quota assigned to it by the DEA.[173]

328. At all relevant times, the RICO Defendants[174] operated as an association-in-fact enterprise formed for the purpose of unlawfully increasing sales, revenues and profits by disregarding their statutory duty to identify, investigate, halt and report suspicious orders of opioids and diversion of their drugs into the illicit market, in order to unlawfully increase the quotas set by the DEA and allow them to collectively benefit from the unlawful formation of a greater pool of prescription opioids from which to profit. The RICO Defendants conducted their pattern of racketeering activity in this jurisdiction and throughout the United States through this enterprise.

329. The opioid epidemic has its origins in the mid-1990s when, between 1997 and 2007, per capita purchase of methadone, hydrocodone, and oxycodone increased 13-fold, 4- fold, and 9-fold, respectively. By 2010, enough prescription opioids were sold in the United States to medicate every adult in the county with a dose of 5 milligrams of hydrocodone

[172] *See* Testimony of Joseph T. Rannazzisi before the Caucus on International Narcotics Control, United State Senate, May 5, 2015 (available at https://www.drugcaucus.senate.gov/sites/default/files/Rannazzisi%20Testimony_0.pdf) (accessed July 13, 2018).
[173] *Id*. (*citing* 21 U.S.C. 842)).
[174] The term "RICO Defendants" shall hereinafter refer to all Defendants, other than Insys Therapeutics, Inc.

every 4 hours for 1 month.[175] On information and belief, the Opioid Diversion Enterprise has been ongoing for at least the last decade.[176]

330. The Opioid Diversion Enterprise was and is a shockingly successful endeavor. It Opioid Diversion Enterprise has been conducting business uninterrupted since its genesis. But, it was not until recently that United States and State regulators finally began to unravel the extent of the enterprise and the toll that it exacted on the American public.

331. At all relevant times, the Opioid Diversion Enterprise: (a) had an existence separate and distinct from each RICO Defendant; (b) was separate and distinct from the pattern of racketeering in which the RICO Defendants engaged; (c) was an ongoing and continuing organization consisting of legal entities, including each of the RICO Defendants; (d) characterized by interpersonal relationships among the RICO Defendants; (e) had sufficient longevity for the enterprise to pursue its purpose; and (f) functioned as a continuing unit. *Turkette*, 452 U.S. at 580; *Boyle*, 556 U.S. at 944 (2009). Each member of the Opioid Diversion Enterprise participated in the conduct of the enterprise, including patterns of racketeering activity, and shared in the astounding growth of profits supplied by fraudulently inflating opioid sales generated as a result of the Opioid Diversion Enterprise's disregard for their duty to prevent diversion of their drugs into the illicit market and then requesting the DEA increase production quotas, all so that the RICO Defendants would have a larger pool of prescription opioids from which to profit.

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[175] Keyes KM, Cerda M, Brady JE, Havens JR, Galea S. Understanding the rural-urban differences in nonmedical prescription opioid use and abuse in the United States. Am J Public Health. 2014;104(2):eS2-9.

[176] Matthew Perrone, Pro-Painkiller echo chamber shaped policy amid drug epidemic, The Center for Public Integrity (September 19, 2016, 12:01 a.m.), https://www.publicintegrity.org/2016/09/19/20201/pro-painkiller-echo-chamber-shaped-policy-amid-drug-epidemic (last accessed Jul. 12, 2018).

332. The Opioid Diversion Enterprise also engaged in efforts to lobby against the DEA's authority to hold the RICO Defendants liable for disregarding their duty to prevent diversion. Members of the Pain Care Forum (described in greater detail below) and the Hea1thcare Distribution Alliance lobbied for the passage of legislation to weaken the DEA's enforcement authority. The Ensuring Patient Access and Effective Drug Enforcement Act significantly reduced the DEA's ability to issue orders to show cause and to suspend and/or revoke registrations[177] The HDA and other members of the Pain Care Forum contributed substantial amounts of money to political campaigns for federal candidates, state candidates, political action committees and political parties. Plaintiff is informed and believe that the Pain Care Forum and their members poured at least $3.5 million into lobbying efforts in this jurisdiction while the HDA devoted over a million dollars a year to its lobbying efforts between 2011 and 2016.

333. The Opioid Diversion Enterprise functioned by selling prescription opioids. While there are some legitimate uses and/or needs for prescription opioids, the RICO Defendants, through their illegal enterprise, engaged in a pattern of racketeering activity, that involves

[177] *See* HDMA is now the Healthcare Distribution Alliance, Pharmaceutical Commerce, (June 13, 2016, updated July 6, 2016), http://pharmaceuticalcommerce.com/business-and-finance/hdma-now-healthcare-distribution-alliance/; Lenny Bernstein & Scott Higham, Investigation: The DEA Slowed Enforcement While the Opioid Epidemic Grew Out of Control, Wash. Post, Oct. 22, 2016, https://www.washingtonpost.com/investigations/the-dea-slowed-enforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13-d7c704ef9fd9_story.html?utm_term=.8f84381a0ebe, (accessed July 13, 2018); Lenny Bernstein & Scott Higham, Investigation: U.S. Senator Calls for Investigation of DEA Enforcement Slowdown Amid Opioid Crisis, Wash. Post, Mar. 6, 2017, https://www.washingtonpost.com/investigations/us-senator-calls-for-investigation-of-dea-enforcement-slowdown/2017/03/06/5846ee60-028b-11e7-b1e9-a05d3c21f7cf_story.html?utm_term=.61f36a18c2c9, (accessed July 13, 2018); Eric Eyre, DEA Agent:"We Had no Leadership" in WV Amid Flood of Pain Pills,Charleston Gazette-Mail, Feb. 18, 2017, https://www.wvgazettemail.com/news/health/dea-agent-we-had-no-leadership-in-wv-amid-flood/article_928e9bcd-e28e-58b1-8e3f-f08288f539fd.html, (accessed July 13, 2018).

a fraudulent scheme to increase revenue by violating State and Federal laws requiring the maintenance of effective controls against diversion of prescription opioids, and the identification, investigation, and reporting of suspicious orders of prescription opioids destined for the illicit drug market. The goal of Defendants' scheme was to increase profits from opioid sales. But, Defendants' profits were limited by the production quotas set by the DEA, so the Defendants refused to identify, investigate and/or report suspicious orders of their prescription opioids being diverted into the illicit drug market. The end result of this strategy was to increase and maintain artificially high production quotas of opioids so that there was a larger pool of opioids for Defendants to manufacture and distribute for public consumption.

334. The Opioid Diversion Enterprise engaged in, and its activities affected, interstate and foreign commerce because the enterprise involved commercial activities across states lines, such as manufacture, sale, distribution, and shipment of prescription opioids throughout the County and this jurisdiction, and the corresponding payment and/or receipt of money from the sale of the same.

335. Within the Opioid Diversion Enterprise, there were interpersonal relationships and common communication by which the RICO Defendants shared information on a regular basis. These interpersonal relationships also formed the organization of the Opioid Diversion Enterprise. The Opioid Diversion Enterprise used their interpersonal relationships and communication network for the purpose of conducting the enterprise through a pattern of racketeering activity.

336. Each of the RICO Defendants had a systematic link to each other through joint participation in lobbying groups, trade industry organizations, contractual relationships and

continuing coordination of activities. The RICO Defendants participated in the operation and management of the Opioid Diversion Enterprise by directing its affairs, as described herein. While the RICO Defendants participated in, and are members of, the enterprise, they each have a separate existence from the enterprise, including distinct legal statuses, different offices and roles, bank accounts, officers, directors, employees, individual personhood, reporting requirements, and financial statements.

337. The RICO Defendants exerted substantial control over the Opioid Diversion Enterprise by their membership in the Pain Care Forum, the HDA, and through their contractual relationships.

338. The Pain Care Forum ("PCF") has been described as a coalition of drug makers, trade groups and dozens of non-profit organizations supported by industry funding. The PCF recently became a national news story when it was discovered that lobbyists for members of the PCF quietly shaped federal and state policies regarding the use of prescription opioids for more than a decade.

339. The Center for Public Integrity and The Associated Press obtained "internal documents shed [ding] new light on how drug makers and their allies shaped the national response to the ongoing wave of prescription opioid abuse."[178] Specifically, PCF members spent over $740 million lobbying in the nation's capital and in all 50 statehouses on an array of issues, including opioid-related measures.[179]

[178] Matthew Perrone, Pro-Painkiller echo chamber shaped policy amid drug epidemic, The Center for Public Integrity (September 19, 2017,12:01 a.m.), https://www.publicintegrity.org/2016/09/19/20201/pro-painkiller-echo-chamber-shaped-policy-amid-drug-epidemic (emphasis added), (accessed July 13, 2018).
[179] *Id*.

340. Not surprisingly, each of the RICO Defendants who stood to profit from lobbying in favor of prescription opioid use is a member of and/or participant in the PCF.[180] In 2012, membership and participating organizations included the HDA (of which all RICO Defendants are members), Endo, Purdue, Johnson & Johnson (the parent company for Janssen Pharmaceuticals), Actavis *(i.e.,* Allergan), and Teva (the parent company of Cephalon).[181] Each of the Manufacturer Defendants worked together through the PCF to advance the interests of the enterprise. But, the Manufacturer Defendants were not alone. The Distributor Defendants actively participated, and continue to participate in the PCF, at a minimum, through their trade organization, the HDA.[182] Plaintiff is informed and believe that the Distributor Defendants participated directly in the PCF as well.

341. The 2012 Meeting Schedule for the Pain Care Forum is particularly revealing on the subject of the Defendants' interpersonal relationships. The meeting schedule indicates that meetings were held in the D.C. office of Powers Pyles Sutter & Verville on a monthly basis, unless otherwise noted. Local members were "encouraged to attend in person" at the monthly meetings. And, the meeting schedule indicates that the quarterly and year-end meetings included a "Guest Speaker."

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[180] PAIN CARE FORUM 2012 Meetings Schedule, (last updated April 2012), http://www.documentcloud.org/documents/3108983-PAIN-CARE-FORUM-Meetings-Schedule-amp.html, (accessed July 13, 2018)

[181] *Id*. Plaintiff is infonned and believes that Mallinckrodt became an active member of the PCF sometime after 2012.

[182] *Id*. The Executive Committee of the HDA (formerly the HDMA) currently includes the Chief Executive Officer, Pharmaceutical Segment for Cardinal Health, Inc., the Group President, Phannaceutical Distribution and Strategic Global Source for AmerisourceBergen Corporation, and the President, U.S. Phannaceutical for McKesson Corporation. Executive Committee, Healthcare Distribution Alliance, https://www.healthcaredistribution.org/about/executive-committee (accessed on July 12, 2018).

342. The 2012 Pain Care Forum Meeting Schedule demonstrates that each of the Defendants participated in meetings on a monthly basis, either directly or through their trade organization, in a coalition of drug makers and their allies whose sole purpose was to shape the national response to the ongoing prescription opioid epidemic, including the concerted lobbying efforts that the PCF undertook on behalf of its members.

343. Second, the HDA -- or Healthcare Distribution Alliance -- led to the formation of interpersonal relationships and an organization between the RICO Defendants. Although the entire HDA membership directory is private, the HDA website confirms that each of the Distributor Defendants and the Manufacturer Defendants named in the Complaint, including Actavis *(i.e.,* Allergan), Endo, Purdue, Mallinckrodt and Cephalon were members of the HDA.[183] And, the HDA and each of the Distributor Defendants, eagerly sought the active membership and participation of the Manufacturer Defendants by advocating that one of the benefits of membership included the ability to develop direct relationships between Manufacturers and Distributors at high executive levels.

344. In fact, the HDA touted the benefits of membership to the Manufacturer Defendants, advocating that membership included the ability to, among other things, "network one on one with manufacturer executives at HDA's members-only Business and Leadership Conference," "networking with HDA wholesale distributor members," "opportunities to host and sponsor HDA Board of Directors events," "participate on HDA committees, task forces and working groups with peers and trading partners," and "make

[183] Manufacturer Membership, Healthcare Distribution Alliance, https://www.healthcaredistribution.org/about/membership/manufacturer (accessed on July 12, 2018).

connections."[184] Clearly, the HDA and the Distributor Defendants believed that membership in the HDA was an opportunity to create interpersonal and ongoing organizational relationships between the Manufacturers and Defendants.

345. The application for manufacturer membership in the HDA further indicates the level of connection that existed between the RICO Defendants.[185] The manufacturer membership application must be signed by a "senior company executive," and it requests that the manufacturer applicant identify a key contact and any additional contacts from within its company. The HDA application also requests that the manufacturer identify its current distribution information and its most recent year end net sales through any HDA distributors, including but not limited to, Defendants AmerisourceBergen, Cardinal Health, and McKesson.[186]

346. After becoming members, the Distributors and Manufacturers were eligible to participate on councils, committees, task forces and working groups, including:

a. Industry Relations Council: "This council, composed of distributor and manufacturer members, provides leadership on pharmaceutical distribution and supply chain issues."[187]

b. Business Technology Committee: "This committee provides guidance to HDA and its members through the development of collaborative e-commerce business solutions. The committee's major areas of focus within pharmaceutical distribution include

[184] Manufacturer Membership Benefits, Healthcare Distribution Alliance, https://www.healthcaredistribution.org/~/media/pdfs/membership/manufacturer-membership-benefits.ashx?la=en (accessed on July 12, 2018).
[185] *Id*.
[186] *Id*.
[187] Councils and Committees, Hea1thcare Distribution Alliance, https://www.healthcaredistribution.org/about/councils-and-committees (accessed on July 12,2018)

information systems, operational integration and the impact of ecommerce." Participation in this committee includes distributors and manufacturer members.[188]

c. Health, Beauty and Wellness Committee: "This committee conducts research, as well as creates and exchanges industry knowledge to help shape the future of the distribution for health, beauty and wellness/consumer products in the healthcare supply chain." Participation in this committee includes distributors and manufacturer members.[189]

d. Logistics Operation Committee: "This committee initiates projects designed to help members enhance the productivity, efficiency and customer satisfaction within the healthcare supply chain. Its major areas of focus include process automation, information systems, operational integration, resource management and quality improvement." Participation in this committee includes distributors and manufacturer members.[190]

e. Manufacturer Government Affairs Advisory Committee: "This committee provides a forum for briefing HDA's manufacturer members on federal and state legislative and regulatory activity affecting the pharmaceutical distribution channel. Topics discussed include such issues as prescription drug traceability, distributor licensing, and FDA and DEA regulation of distribution, importation and Medicaid/Medicare reimbursement." Participation ill this committee includes manufacturer members.[191]

f. Bar Code Task Force: Participation includes Distributor, Manufacturer and Service Provider Members.[192]

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[188] *Id.*
[189] *Id.*
[190] *Id.*
[191] *Id.*
[192] *Id.*

g. eCommerce Task Force: Participation includes Distributor, Manufacturer and Service Provider Members.[193]

h. ASN Working Group: Participation includes Distributor, Manufacturer and Service Provider Members.[194]

347. Contracts and Chargebacks Working Group: "This working group explores how the contract administration process can be streamlined through process improvements or technical efficiencies. It also creates and exchanges industry knowledge of interest to contract and chargeback professionals." Participation includes Distributor and Manufacturer Members.[195]

348. The councils, committees, task forces and working groups provided the Manufacturer and Distributor Defendants with the opportunity to work closely together in shaping their common goals and forming the enterprise's organization.

349. The HDA also offers a multitude of conferences, including annual business and leadership conferences. The HDA, and the Distributor Defendants advertise these conferences to the Manufacturer Defendants The conferences also gave the Manufacturer and Distributor Defendants "unmatched opportunities to network with [their 1 peers and trading partners at all levels of the healthcare distribution industry."[196] The HDA and its conferences were significant opportunities for the Manufacturer and Distributor Defendants to interact at a high-level of leadership. Upon information and belief,

[193] *Id*
[194] *Id*.
[195] *Id*.
[196] *Id*.

Manufacturer Defendants embraced this opportunity by attending and sponsoring these events.

350. Third, the RICO Defendants maintained their interpersonal relationships by working together and exchanging information and driving the unlawful sales of their opioids through their contractual relationships, including chargebacks and vault security programs.

351. The Manufacturer Defendants engaged in an industry-wide practice of paying rebates and/or chargebacks to the Distributor Defendants for sales of prescription opioids.[197] As reported in the Washington Post, identified by Senator McCaskill, and acknowledged by the HDA, there is an industry-wide practice whereby the Manufacturers paid the Distributors rebates and/or chargebacks on their prescription opioid sales.[198] On information and belief, these contracts were negotiated at the highest levels, demonstrating ongoing relationships between the Manufacturer and Distributor Defendants. In return for the rebates and chargebacks, the Distributor Defendants provided the Manufacturer Defendants with detailed information regarding their prescription opioid sales, including

[197] Lenny Bernstein & Scott Higham, The government's struggle to hold opioid manufacturers accountable, The Washington Post, (April 2, 2017), https://www.washingtonpost.com/graphics/investigations/dea-mallinckrodt/?utm_term=.ed5a9c8f3a6f, (accessed July 13, 2018); *see also*, Letter from Sen. Claire McCaskill, (July 27, 2017), https://www.mccaskill.senate.gov/imo/media/image/july-opioid-investigation-letter-manufacturers.png; Letter from Sen. Claire McCaskill, (July 27, 2017), https://www.mccaskill.senate.gov/imo/media/image/july-opioid-investigation-letter-manufacturers.png; Letters From Sen. Claire McCaskill, (March 28, 2017), https://www.hsgac.senate.gov/imo/media/doc/McCaskill%20Opioid%20Letters.pdf; Purdue Managed Markets, Purdue Pharma, (accessed on July 12, 2018),http://www.purduepharma.com/payers/managed-markets/.

[198] *Id*.

purchase orders, acknowledgements, ship notices, and invoices.[199] The Manufacturer Defendants used this information to gather high-level data regarding overall distribution and direct the Distributor Defendants on how to cost effectively sell the prescription opioids.

352. The contractual relationships among the RICO Defendants also include vault security programs. The RICO Defendants are required to maintain certain security protocols and storage facilities for the manufacture and distribution of their opiates. Plaintiff is informed and believes that manufacturers negotiated agreements whereby the Manufacturers installed security vaults for Distributors in exchange for agreements to maintain minimum sales performance thresholds. Plaintiff is informed and believes that these agreements were used by the RICO Defendants as a tool to violate their reporting and diversion duties in order to reach the required sales requirements.

353. Taken together, the interaction and length of the relationships between and among the Manufacturer and Distributor Defendants reflects a deep level of interaction and cooperation between two groups in a tightly knit industry. The Manufacturer and Distributor Defendants were not two separate groups operating in isolation or two groups forced to work together in a closed system. The RICO Defendants operated together as a united entity, working together on multiple fronts, to engage in the unlawful sale of prescription opioids. The HDA and the Pain Care Forum are but two examples of the overlapping relationships, and concerted joint efforts to accomplish common goals and

[199] Webinars, Healthcare Distribution Alliance, https://www.healthcaredistribution.org/resources/webinar-leveraging-edi (accessed on July 12, 2018).

demonstrates that the leaders of each of the RICO Defendants was in communication and cooperation.

354. According to articles published by the Center for Public Integrity and The Associated Press, the Pain Care Forum -- whose members include the Manufacturers and the Distributors' trade association has been lobbying on behalf of the Manufacturers and Distributors for "more than a decade."[200] And, from 2006 to 2016 the Distributors and Manufacturers worked together through the Pain Care Forum to spend over $740 million lobbying in the nation's capital and in all 50 statehouses on issues including opioid-related measures.[201] Similarly, the HDA has continued its work on behalf of Distributors and Manufacturers, without interruption, since at least 2000, if not longer.[202]

355. As described above, the RICO Defendants began working together as early as 2006 through the Pain Care Forum and/or the HDA to promote the common purpose of their enterprise. Plaintiff is informed and believes that the RICO Defendants worked together as an ongoing and continuous organization throughout the existence of their enterprise.

II. Conduct of the Opioid Diversion Enterprise

356. During the time period alleged in this Complaint, the RICO Defendants exerted control over, conducted and/or participated in the Opioid Diversion Enterprise by fraudulently failing to comply with their Federal and State obligations to identify, investigate and report suspicious orders of opioids in order to prevent diversion of those

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[200] Matthew Perrone, Pro-Painkiller echo chamber shaped policy amid drug epidemic, The Center for Public Integrity (September 19, 2017, 12:01 a.m.), https://www.publicintegrity.org/2016/09/19/20201/pro-painkiller-echo-chamber-shaped-policy-amid-drug-epidemic, (accessed on July 12, 2018).

[201] *Id*.

[202] HDA History, Healthcare Distribution Alliance, https://www.healthcaredistribution.org/about/hda-history (accessed on July 12, 2018).

highly addictive substances into the illicit market, to halt such unlawful sales and, in doing so, to increase production quotas and generate unlawful profits, as follows:

a. Defendants disseminated false and misleading statements to the public claiming that they were complying with their obligations to maintain effective controls against diversion of their prescription opioids.

b. Defendants disseminated false and misleading statements to the public claiming that they were complying with their obligations to design and operate a system to disclose to the registrant suspicious orders of their prescription opioids.

c. Defendants disseminated false and misleading statements to the public claiming that they were complying with their obligation to notify the DEA of any suspicious orders or diversion of their prescription opioids.

d. Defendants paid nearly $800 million dollars to influence local, state and federal governments through joint lobbying efforts as part of the Pain Care Forum. The RICO Defendants were all members of their Pain Care Forum either directly or indirectly through the HDA. The lobbying efforts of the Pain Care Forum and its members, included efforts to pass legislation making it more difficult for the DEA to suspend and/or revoke the Manufacturers' and Distributors' registrations for failure to report suspicious orders of opioids.

357. The RICO Defendants exercised control and influence over the distribution industry by participating and maintaining membership in the HDA.

358. The RICO Defendants applied political and other pressure on the DOJ and DEA to halt prosecutions for failure to report suspicious orders of prescription opioids and lobbied Congress to strip the DEA of its ability to immediately suspend registrations pending

investigation by passing the "Ensuring Patient Access and Effective Drug Enforcement Act."[203]

359. The RICO Defendants engaged in an industry-wide practice of paying rebates and chargebacks to incentivize unlawful opioid prescription sales. Plaintiff is informed and believes that the Manufacturer Defendants used the chargeback program to acquire detailed high-level data regarding sales of the opioids they manufactured. And, Plaintiff is informed and believes that the Manufacturer Defendants used this high-level information to direct the Distributor Defendants' sales efforts to regions where prescription opioids were selling in larger volumes.

360. The Manufacturer Defendants lobbied the DEA to increase Aggregate Production Quotas, year after year by submitting net disposal information that the Manufacturer Defendants knew included sales that were suspicious and involved the diversion of opioids that had not been properly investigated or reported by the RICO Defendants.

361. The Distributor Defendants developed "know your customer" questionnaires and files. This information, compiled pursuant to comments from the DEA in 2006 and 2007 was intended to help the RICO Defendants identify suspicious orders or customers who

[203] *See* HDMA is now the Healthcare Distribution Alliance, Pharmaceutical Commerce, (June 13, 2016, updated July 6, 2016), http://pharmaceuticalcommerce.com/business-and-finance/hdma-now-healthcare-distribution-alliance; Lenny Bernstein & Scott Higham, Investigation: The DEA Slowed Enforcement While the Opioid Epidemic Grew Out of Control, Wash. Post, Oct. 22, 2016, https://www.washingtonpost.com/investigations/the-dea-slowed-enforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13-d7c704ef9fd9_story.html?utm_term=.8f84381a0ebe (accessed July 16, 2018); Lenny Bernstein & Scott Higham, Investigation: U.S. Senator Calls for Investigation of DEA Enforcement Slowdown Amid Opioid Crisis, Wash. Post, Mar. 6, 2017, https://www.washingtonpost.com/investigations/us-senator-calls-for-investigation-of-dea-enforcement-slowdown/2017/03/06/5846ee60-028b-11e7-b1e9-a05d3c21f7cf_story.html?utm_term=.61f36a18c2c9 (accessed July 16, 2018); Eric Eyre, DEA Agent: "We Had no Leadership" in WV Amid Flood of Pain Pills, Charleston Gazette-Mail, Feb. 18, 2017, http://www.wvgazettemail.com/news/20170218/dea-agent-we-had-no-/eadership-in-wv-amid-flood-of-pain-pills-. (last accessed Jul. 12, 2018)

were likely to divert prescription opioids.[204] On information and belief, the "know your customer" questionnaires informed the RICO Defendants of the number of pills that the pharmacies sold, how many non-controlled substances are sold compared to controlled substances, whether the pharmacy buys from other distributors, the types of medical providers in the area, including pain clinics, general practitioners, hospice facilities, cancer treatment facilities, among others, and these questionnaires put the recipients on notice of suspicious orders.

362. The RICO Defendants refused to identify, investigate and report suspicious orders to the DEA when they became aware of the same despite their actual knowledge of drug diversion rings. The RICO Defendants refused to identify suspicious orders and diverted drugs despite the DEA issuing final decisions against the Distributor Defendants in 178 registrant actions between 2008 and 2012[205] and 117 recommended decision in registrant actions from The Office of Administrative Law Judges. These numbers include 76 actions involving orders to show cause and 41 actions involving immediate suspension orders -- all for failure to report suspicious orders.[206]

363. Defendants' scheme had decision-making structure that was driven by the Manufacturer Defendants and corroborated by the Distributor Defendants. The

[204]Suggested Questions a Distributor should ask prior to shipping controlled substances, Drug Enforcement Administration (available at https://www.deadiversion.usdoj.gov/mtgs/pharm_industry/14th_pharm/levinl_ques.pdf); Richard Widup, Jr., Kathleen H. Dooley, Esq. Pharmaceutical Production Diversion: Beyond the PDMA, Purdue Pharma and McQuite Woods LLC, (available at https://www.mcguirewoods.com/newsresources/publications/lifesciences/product_diversion_beyond_pdma.pdf).

[205] Evaluation and Inspections Div., Office of the Inspector Gen., U.S. Dep't of Justice, The Drug Enforcement Administration's Adjudication of Registrant Actions 6 (2014), https://oig.justice.gov/reportsl2014/e1403.pdf.

[206] *Id*.

Manufacturer Defendants worked together to control the State and Federal Government's response to the manufacture and distribution of prescription opioids by increasing production quotas through a systematic refusal to maintain effective controls against diversion, and identify suspicious orders and report them to the DEA.

364. The RICO Defendants worked together to control the flow of information and influence state and federal governments and political candidates to pass legislation that was pro- opioid. The Manufacturer and Distributor Defendants did this through their participation in the Pain Care Forum and Healthcare Distributors Alliance.

365. The RICO Defendants also worked together to ensure that the Aggregate Production Quotas, Individual Quotas and Procurement Quotas allowed by the DEA stayed high and ensured that suspicious orders were not reported to the DEA. By not reporting suspicious orders or diversion of prescription opioids, the RICO Defendants ensured that the DEA had no basis for refusing to increase or decrease the production quotas for prescription opioids due to diversion of suspicious orders. The RICO Defendants influenced the DEA production quotas in the following ways:

a. The Distributor Defendants assisted the enterprise and the Manufacturer Defendants in their lobbying efforts through the Pain Care Forum;

b. The Distributor Defendants invited the participation, oversight and control of the Manufacturer Defendants by including them in the HDA, including on the councils, committees, task forces, and working groups;

c. The Distributor Defendants provided sales information to the Manufacturer Defendants regarding their prescription opioids, including reports of all opioids prescriptions filled by the Distributor Defendants;

d. The Manufacturer Defendants used a chargeback program to ensure delivery of the Distributor Defendants' sales information;

e. The Manufacturer Defendants obtained sales information from QuintilesIMS (formerly IMS Health) that gave them a "stream of data showing how individual doctors across the nation were prescribing opioids."[207]

f. The Distributor Defendants accepted rebates and chargebacks for orders of prescription opioids;

g. The Manufacturer Defendants used the Distributor Defendants' sales information and the data from QuintilesIMS to instruct the Distributor Defendants to focus their distribution efforts to specific areas where the purchase of prescription opioids was most frequent;

h. The RICO Defendants identified suspicious orders of prescription opioids and then continued filling those unlawful orders, without reporting them, knowing that they were suspicious and/or being diverted into the illicit drug market;

i. The RICO Defendants refused to report suspicious orders of prescription opioids despite repeated investigation and punishment of the Distributor Defendants by the DEA for failure to report suspicious orders; and

j. The RICO Defendants withheld information regarding suspicious orders and illicit diversion from the DEA because it would have revealed that the "medical need" for and the net disposal of their drugs did not justify the production quotas set by the DEA.

[207] Harriet Ryan, et al., More than 1 million OxyContin pills ended up in the hands of criminals and addicts. What the drugmaker knew, Los Angeles Times, (July 10,2016), http://www.latimes.com/projects/la-me-oxycontin-part2/ (accessed July 12, 2018)

366. The scheme devised and implemented by the RICO Defendants amounted to a common course of conduct characterized by a refusal to maintain effective controls against diversion, and all designed and operated to ensure the continued unlawful sale of controlled substances.

III. PATTERN OF RACKETEERING ACTIVITY

367. The Rico Defendants conducted and participated in the conduct of the Opioid Diversion Enterprise through a pattern of racketeering activity as defined in 18 U.S.C. § 1961(B), including mail fraud (18 U.S.C. § 1341) and wire fraud (18 U.S.C. § 1343); and 18 § 1961(D) by the felonious manufacture, importation, receiving, concealment buying selling, or otherwise dealing in a controlled substance or listed chemical (as defined in section 102 of the Controlled Substance Act), punishable under any law of the United States.

a. The RICO Defendants Engaged in Mail and Wire Fraud.

368. The RICO Defendants carried out, or attempted to carry out, a scheme to defraud federal and state regulators, and the American public by knowingly conducting or participating in the conduct of the Opioid Diversion Enterprise through a pattern of racketeering activity within the meaning of 18 U.S.C. § 1961(1) that employed the use of mail and wire facilities, in violation of 18 U.S.C. § 1341 (mail fraud) and § 1343 (wire fraud).

369. The RICO Defendants committed, conspired to commit, and/or aided and abetted in the commission of at least two predicate acts of racketeering activity (i.e. violations of 18 U.S.C. §§ 1341 and 1343) within the past ten years. The multiple acts of racketeering activity that the RICO Defendants committed, or aided and abetted in the commission of, were related to each other, posed a threat of continued racketeering activity, and therefore

constitute a "pattern of racketeering activity." The racketeering activity was made possible by the RICO Defendants' regular use of the facilities, services, distribution channels, and employees of the Opioid Diversion Enterprise. The RICO Defendants participated in the scheme to defraud by using mail, telephone and the Internet to transmit mailings and wires in interstate or foreign commerce.

370. The RICO Defendants used, directed the use of, and/or caused to be used, thousands of interstate mail and wire communications in service of their scheme through virtually uniform misrepresentations, concealments and material omissions regarding their compliance with their mandatory reporting requirements and the actions necessary to carry out their unlawful goal of selling prescription opioids without reporting suspicious orders or the diversion of opioids into the illicit market.

371. In devising and executing the illegal scheme, the RICO Defendants devised and knowingly carried out a material scheme and/or artifice to defraud by means of materially false or fraudulent pretenses, representations, promises, or omissions of material facts. For the purpose of executing the illegal scheme, the RICO Defendants committed these racketeering acts, which number in the thousands, intentionally and knowingly with the specific intent to advance the illegal scheme.

372. The RICO Defendants' predicate acts of racketeering (18 U.S.C. § 1961(1)) include, but are not limited to:

a. Mail Fraud: The RICO Defendants violated 18 U.S.C. § and/or received, materials via U.S. mail or commercial interstate carriers for the purpose of executing the unlawful scheme to design, manufacture, market, and sell the prescription opioids by means of false pretenses, misrepresentations, promises, and omissions.

b. Wire Fraud: The RICO Defendants violated 18 U.S.C. § 1343 by transmitting and/or receiving, or by causing to be transmitted and/or received, materials by wire for the purpose of executing the unlawful scheme to design, manufacture, market, and sell the prescription opioids by means of false pretenses, and misrepresentations, promises, and omissions.

373. The RICO Defendants' use of the mail and wires includes, but is not limited to, the transmission, delivery, or shipment of the following by the Manufacturers, Distributors, or third parties that were foreseeably caused to be sent as a result of the RICO Defendants' illegal scheme, including but not limited to:

a. The prescription opioids themselves;

b. Documents and communications that facilitated the manufacture, purchase and unlawful sale of prescription opioids;

c. Defendants' DEA registrations;

d. Documents and communications that supported and/or facilitated Defendants' DEA registrations;

e. Documents and communications that supported and/or facilitated the Defendants' request for higher aggregate production quotas, individual production quotas, and procurement quotas;

f. Defendants' records and reports that were required to be submitted to the DEA pursuant to 21 U.S.C. § 827;

g. Documents and communications related to the Defendants' mandatory DEA reports pursuant to 21 U.S.C. § 823 and 21 C.F.R. § 1301.74;

h. Documents intended to facilitate the manufacture and distribution of Defendants' prescription opioids, including bills of lading, invoices, shipping records, reports and correspondence;

i. Documents for processing and receiving payment for prescription opioids;

j. Payments from the Distributors to the Manufacturers;

k. Rebates and chargebacks from the Manufacturers to the Distributors;

l. Payments to Defendants' lobbyists through the Pain Care Forum;

m. Payments to Defendants' trade organizations, like the HDA, for memberships and/or sponsorships;

n. Deposits of proceeds from Defendants' manufacture and distribution of prescription opioids; and

o. Other documents and things, including electronic communications.

374. On information and belief, the RICO Defendants (and/or their agents), for the purpose of executing the illegal scheme, sent and/or received (or caused to be sent and/or received) by mail or by private or interstate carrier, shipments of prescription opioids and related documents by mail or by private carrier affecting interstate commerce, including the following:

375. Purdue manufactures multiple forms of prescription opioids, including but not limited to: OxyContin, MS Contin, Dilaudid/Dilaudid HP, Butrans, Hysingla ER, and Targiniq ER. Purdue manufactured and shipped these prescription opioids to the Distributor Defendants.

376. The Distributor Defendants shipped Purdue's prescription opioids throughout the United States.

377. Cephalon manufactures multiple forms of prescription opioids, including but not limited to: Actiq and Fentora. Cephalon manufactured and shipped these prescription opioids to the Distributor Defendants.

378. The Distributor Defendants shipped Teva' s prescription opioids throughout the United States.

379. Janssen manufactures prescription opioids known as Duragesic. Janssen manufactured and shipped its prescription opioids to the Distributor Defendants.

380. The Distributor Defendants shipped Janssen's prescription opioids throughout the United States.

381. Endo manufactures multiple forms of prescription opioids, including but not limited to: Opana/Opana ER, Percodan, Percocet, and Zydone. Endo manufactured and shipped its prescription opioids to the Distributor Defendants.

382. The Distributor Defendants shipped Janssen's prescription opioids throughout the United States.

383. Actavis manufactures multiple forms of prescription opioids, including but not limited to: Kadin and Norco, as well as generic versions of the drugs known as Kadian, Duragesic and Opana. Actavis manufactured and shipped its prescription opioids to the Distributor Defendants.

384. The Distributor Defendants shipped Actavis' prescription opioids throughout the United States.

385. Mallinckrodt manufactures multiple forms of prescription opioids, including but not limited to: Exalgo and Roxicodone.

386. The Distributor Defendants shipped Mallinckrodt's prescription opioids throughout the United States.

387. The RICO Defendants also used the internet and other electronic facilities to carry out their scheme and conceal the ongoing fraudulent activities. Specifically, the RICO Defendants made misrepresentations about their compliance with Federal and State laws requiring them to identify, investigate and report suspicious orders of prescription opioids and/or diversion of the same into the illicit market.

388. At the same time, the RICO Defendants misrepresented the superior safety features of their order monitoring programs, ability to detect suspicious orders, commitment to preventing diversion of prescription opioids and that they complied with all state and federal regulations regarding the identification and reporting of suspicious orders of prescription opioids.

389. Plaintiff is also informed and believes that the RICO Defendants utilized the internet and other electronic resources to exchange communications, to exchange information regarding prescription opioid sales, and to transmit payments and rebates/chargebacks.

390. The RICO Defendants also communicated by U.S. Mail, by interstate facsimile, and by interstate electronic mail and with various other affiliates, regional offices, regulators, distributors, and other third-party entities in furtherance of the scheme.

391. The mail and wire transmissions described herein were made in furtherance of Defendants' scheme and common course of conduct to deceive regulators and the public that Defendants were complying with their state and federal obligations to identify and report suspicious orders of prescription opioids all while Defendants were knowingly

allowing millions of doses of prescription opioids to divert into the illicit drug market. The RICO Defendants' scheme and common course of conduct was intended to increase or maintain high production quotas for their prescription opioids from which they could profit.

392. Many of the precise dates of the fraudulent uses of the U.S. mail and interstate wire facilities have been deliberately hidden, and cannot be alleged without access to Defendants' books and records. But, Plaintiff has described the types of, and in some instances, occasions on which the predicate acts of mail and/or wire fraud occurred. They include thousands of communications to perpetuate and maintain the scheme, including the things and documents described in the preceding paragraphs.

393. The RICO Defendants did not undertake the practices described herein in isolation, but as part of a common scheme. These actions violate 18 U.S.C. § 1962(c). Various other persons, firms, and corporations, including third-party entities and individuals not named as defendants in this Complaint, may have contributed to and/or participated in the scheme with the RICO Defendants in these offenses and have performed acts in furtherance of the scheme to increase revenues, increase market share, and/or minimize the losses for the RICO Defendants.

394. The RICO Defendants aided and abetted others in the violations of the above laws, thereby rendering them indictable as principals in the 18 U.S.C. §§ 1341 and 1343 offenses.

395. The RICO Defendants hid from the general public, and suppressed and/or ignored warnings from third parties, whistleblowers and governmental entities, about the reality of the suspicious orders that the RICO Defendants were filling on a daily basis – leading to the diversion of a tens of millions of doses of prescription opioids into the illicit market.

396. The RICO Defendants, with knowledge and intent, agreed to the overall objective of their fraudulent scheme and participated in the common course of conduct to commit acts of fraud and indecency in manufacturing and distributing prescription opioids.

397. Indeed, for the Defendants' fraudulent scheme to work, each of the Defendants had to agree to implement similar tactics regarding marketing prescription opioids and refusing to report suspicious orders.

398. As described herein, the RICO Defendants engaged in a pattern of related and continuous predicate acts for years. The predicate acts constituted a variety of unlawful activities, each conducted with the common purpose of obtaining significant monies and revenues from the sale of their highly addictive and dangerous drugs. The predicate acts also had the same or similar results, participants, victims, and methods of commission. The predicate acts were related and not isolated events.

399. The predicate acts all had the purpose of generating significant revenue and profits for the RICO Defendants while Plaintiff was left with substantial monetary losses through the damage that the prescription opioid epidemic caused. The predicate acts were committed or caused to be committed by the RICO Defendants through their participation in the Opioid Diversion Enterprise and in furtherance of its fraudulent scheme.

400. The pattern of racketeering activity alleged herein and the Opioid Diversion Enterprise are separate and distinct from each other. Likewise, Defendants are distinct from the enterprise.

401. The pattern of racketeering activity alleged herein is continuing as of the date of this Complaint and, upon information and belief, will continue into the future.

402. Many of the precise dates of the RICO Defendants' criminal actions at issue here have been hidden and cannot be alleged without access to Defendants' books and records. Indeed, an essential part of the successful operation of the Opioids Addiction and Opioid Diversion Enterprise alleged herein depended upon secrecy.

403. Each instance of racketeering activity alleged herein was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, including the Plaintiff and the proposed Class members. Defendants calculated and intentionally crafted the Opioid Diversion Enterprise and their scheme to increase and maintain their increased profits, without regard to effects such as behavior would have on consumers, Plaintiff, or the proposed Class members. In designing and implementing the scheme, at all times Defendants were cognizant of the fact that those in the manufacturing and distribution chain rely on the integrity of the pharmaceutical companies and ostensibly neutral third parties to provide objective and reliable information regarding Defendants' products and their manufacture and distribution of those products.

404. By intentionally refusing to report and halt suspicious orders of their prescription opioids, Defendants engaged in a fraudulent scheme and unlawful course of conduct consulting a pattern of racketeering activity.

405. It was foreseeable to Defendants that refusing to report and halt suspicious orders, as required by the CSA and Code of Federal Regulation, would harm Plaintiff as set out herein, by allowing the flow of prescription opioids from appropriate medical channels into illicit drug market.

406. The last racketeering incident occurred within five years of the commission of a prior incident of racketeering.

b. The RICO Defendants Manufactured, Sold and/or Dealt in Controlled Substances and Their Crimes Are Punishable as Felonies

407. The RICO Defendants conducted and participated in the conduct of the affairs of the Opioid Diversion Enterprise through a pattern of racketeering activity as defines in 18 U.S.C. § 1961 (D) by the felonious manufacturer, importation, receiving, concealment, buying, selling, or otherwise dealing in a controlled substance or listed chemical (as defined in section 102 of the Controlled Substance Act), punishable under any law of the United States.

408. The RICO Defendants committed crimes that are punishable as felonies under the laws of the United States. Specifically, 21 U.S.C. § 483(a)(4) makes it unlawful for any person to knowingly or intentionally furnish false or fraudulent information in, or omit any material information from, any application, report, record or other document required to be made, kept or filed under this subchapter. A violation of section 483(a)(4) is punishable by up to four years in jail, making it a felony. 21 U.S.C. § 483(d)(1).

409. Each of the RICO Defendants qualify as registrants under the CSA. Their status as registrants under the CSA requires that they maintain effective controls against diversion of controlled substances in schedule I or II, design and operate a system to disclose to the registrant suspicious orders of controlled substances. and inform the DEA of suspicious orders when discovered by the registrant. 21 U.S.C. § 823; 21 C.F.R. § 1301.74(b).

410. Pursuant to the CSA and the Code of Federal Regulations, the RICO Defendants were required to make reports to the DEA of any suspicious orders identified through the design and operation of their system to disclose suspicious orders.

411. The RICO Defendants knowingly and intentionally furnished false or fraudulent information in their reports to the DEA about suspicious orders, and/or omitted material information from reports, records and other document required to be filed with the DEA including the Manufacturer Defendants' applications for production quotas. Specifically, the RICO Defendants were aware of suspicious orders of prescription opioids and the diversion of their prescription opioids into the illicit market, and failed to report this information to the DEA in their mandatory reports and their applications for production quotas.

412. For example, The DEA and DOJ began investigating McKesson in 2013 regarding its monitoring and reporting of suspicious controlled substances orders. On April 23, 2015, McKesson filed a Form-8-K announcing a settlement with the DEA and DOJ wherein it admitted to violating the CSA and agreed to pay $150 million and have some of its DEA registrations suspended on a staggered basis. The settlement was finalized on January 17, 2017.[208]

413. Purdue's experience in Los Angeles is another striking example of Defendants' willful violation of the CSA and Code of Federal Regulations as it relates to reporting suspicious orders of prescription opioids. In 2016, the Los Angeles Times reported that Purdue was aware of a pill mill operating out of Los Angeles yet failed to alert the DEA.[209]

[208] McKesson, McKesson Finalizes Settlement with U.S. Department of Justice and U.S. Drug Enforcement Administration to Resolve Past Claims, About McKesson I Newsroom I Press Releases, (January 17, 2017), http://www.mckesson.com/about-mckesson/newsroom/press-releasea/2017/mckesson-finalizes-settlement-with-doj-and-dea-to-resolve-past-claims/ (last accessed July 12, 2018).

[209] Harriet Ryan, et al., More than 1 million OxyContin pills ended up in the hands of criminals and addicts. What the drugmaker knew, Los Angeles Times, (July 10,2016), http://www.latimes.com/projects/la-me-oxycontin-part2/ (accessed July 12, 2018).

The LA Times uncovered that Purdue began tracking a surge in prescriptions in Los Angeles, including one prescriber in particular. A Purdue sales manager spoke with company officials in 2009 about the prescriber, asking "Shouldn't the DEA be contacted about this?" and adding that she felt "very certain this is an organized drug ring."[210] Despite knowledge of the staggering amount of pills being issued in Los Angeles, and internal discussion of the problem, "Purdue did not shut off the supply of highly addictive OxyContin and did not tell authorities what it knew about Lake Medical until several years later when the clinic was out of business and its leaders indicted. By that time, 1.1 million pills had spilled into the hands of Armenian mobsters, the Crips gang and other criminals."[211]

414. Finally, Mallinckrodt was recently the subject of a DEA and Senate investigation for its opioid practices. Specifically, in 2011, the DEA targeted Mallinckrodt arguing that it ignored its responsibility to report suspicious orders as 500 million of its pills ended up in Florida between 2008 and 2012.[212] After six years of DEA investigation, Mallinckrodt agreed to a settlement involving a $35 million fine. Federal prosecutors summarized the case by saying that Mallinckrodt's response was that everyone knew what was going on in Florida but they had no duty to report it.[213]

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[210] *Id.*
[211] *Id.*
[212] Lenny Bernstein & Scott Higham, The government's struggle to hold opioid manufacturers accountable, The Washington Post, (April 2, 2017), https://www.washingtonpost.com/graphics/investigations/dea-mallinckrodt/?noredirect=on&utm_term=.f5d1277089b6 (accessed July 13, 2018). This number accounted for 66% of all oxycodone sold in the state of Florida during that time.
[213] *Id.*

415. Plaintiff is informed and believes that the foregoing examples reflect the RICO Defendants' pattern and practice of willfully and intentionally omitting information from their mandatory reports to the DEA as required by 21 C.F.R. § 1301.74. This conclusion is supported by the sheer volume of enforcement actions available in the public record against the Distributor Defendants.[214] For example:

a. On April 24, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the AmerisourceBergen Orlando, Florida distribution center ("Orlando Facility") alleging failure to maintain effective controls against diversion of controlled substances. On June 22, 2007, AmerisourceBergen entered into a settlement that resulted in the suspension of its DEA registration;

b. On November 28, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Auburn, Washington Distribution Center ("Auburn Facility") for failure to maintain effective controls against diversion of hydrocodone;

c. On December 5, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Lakeland, Florida Distribution Center ("Lakeland Facility") for failure to maintain effective controls against diversion of hydrocodone;

d. On December 7, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Swedesboro, New Jersey Distribution

[214] Evaluation and Inspections Div., Office of the Inspector Gen., U.S. Dep't of Justice, The Drug Enforcement Administration's Adjudication of Registrant Actions 6 (2014),https://oig.justice.gov/reports/2014/e1403.pdf.

Center ("Swedesboro Facility") for failure to maintain effective controls against diversion of hydrocodone;

e. On January 30, 2008, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Stafford, Texas Distribution Center ("Stafford Facility") for failure to maintain effective controls against diversion of hydrocodone;

f. On May 2, 2008, McKesson Corporation entered into an *Administrative Memorandum of Agreement* ("2008 MOA") with the DEA which provided that McKesson would "maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious orders required by 21 C.F.R. § 1301.74(b), and follow the procedures established by its Controlled Substance Monitoring Program";

g. On September 30, 2008, Cardinal Health entered into a *Settlement and Release Agreement and Administrative Memorandum of Agreement* with the DEA related to its Auburn Facility, Lakeland Facility, Swedesboro Facility and Stafford Facility. The document also referenced allegations by the DEA that Cardinal failed to maintain effective controls against the diversion of controlled substances at its distribution facilities located in McDonough, Georgia ("McDonough Facility"), Valencia, California ("Valencia Facility") and Denver, Colorado ("Denver Facility");

h. On February 2, 2012, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Lakeland, Florida Distribution Center ("Lakeland Facility") for failure to maintain effective controls against diversion of oxycodone;

i. On December 23, 2016, Cardinal Health agreed to pay a $44 million fine to the DEA to resolve the civil penalty portion of the administrative action taken against its Lakeland, Florida Distribution Center; and

j. On January 5, 2017, McKesson Corporation entered into an *Administrative Memorandum Agreement* with the DEA wherein it agreed to pay a $150,000,000 civil penalty for violation of the 2008 MOA as well as failure to identify and report suspicious orders at its facilities in Aurora CO, Aurora IL, Delran NJ, LaCrosse WI, Lakeland FL, Landover MD, La Vista NE, Livonia MI, Methuen MA, Santa Fe Springs CA, Washington Courthouse OH and West Sacramento CA.

416. These actions against the Distributor Defendants confirm that the Distributors knew they had a duty to maintain effective controls against diversion, design and operate a system to disclose suspicious orders, and to report suspicious orders to the DEA. These actions also demonstrate, on information and belief, that the Manufacturer Defendants were aware of the enforcement against their Distributors and the diversion of the prescription opioids and a corresponding duty to report suspicious orders.

417. The pattern of racketeering activity alleged herein is continuing as of the date of this Complaint and, upon information and belief, will continue into the future.

418. Many of the precise dates of Defendants' criminal actions at issue herein were hidden and cannot be alleged without access to Defendants' books and records. Indeed, an essential part of the successful operation of the Opioid Diversion Enterprise depended upon the secrecy of the participants in that enterprise.

419. Each instance of racketeering activity alleged herein was related, had similar purposes, involved the same or similar participants and methods of commission, and had

similar results affecting similar victims, including consumers and Plaintiff and the proposed Class members. Defendants calculated and intentionally crafted the diversion scheme to increase and maintain profits from unlawful sales of opioids, without regard to the effect such behavior would have on consumers, Plaintiff, and the proposed Class members.

420. By intentionally refusing to report and halt suspicious orders of their prescription opioids, Defendants engaged in a fraudulent scheme and unlawful course of conduct constituting a pattern of racketeering activity.

421. It was foreseeable to Defendants that refusing to report and halt suspicious orders, as required by the CSA and Code of Federal Regulations would harm Plaintiff as set out herein by allowing the flow of prescription opioids from appropriate medical channels into the illicit drug market.

422. The last racketeering incident occurred within five years of the commission of a prior incident of racketeering.

CLASS ALLEGATIONS

423. This action is brought as a plaintiff's class action pursuant to Federal Rule of Civil Procedure 23(b)(3). Plaintiff brings this action on their own behalf, and on behalf of all others similarly situated, as representatives of the following Class:

> All emergency room physicians in the United States which treated patients with opioid conditions within the applicable statute of limitations.
>
> Excluded from the Class are any emergency room physicians directly or indirectly owned or operated by Defendants or Defendants' affiliated entities.

424. The members of the Class are readily identifiable from public records.

425. Upon information and belief, the Class consists of thousands of members, and is therefore so numerous that individual joinder of all members is impracticable. The members of the Class are geographically dispersed throughout the United States.

426. There are questions of law and fact common to the Class, which predominate over any questions affecting only individual members of the Class. The wrongs suffered and remedies sought by Plaintiff and the other members of the Class are premised upon a uniform unlawful scheme perpetuated by Defendants. The sole question affecting only individual members of the Class is the exact monetary recovery to which each Class member is entitled. Plaintiff's and the Class members' use of uniform billing codes for patients with opioid conditions will render this determination a simple mechanical one. Questions common to the Class include, but are not limited to, the following:

a. Did the Manufacturer Defendants use false and deceptive statements and omissions to market opioids?

b. Did the Manufacturer Defendants market opioids by misrepresenting the risks and benefits of opioids?

c. Did the Manufacturer Defendants and the Distributor Defendants fail to monitor, detect, investigate, refuse to fill, and report suspicious orders of prescription opioids?

d. Did the Manufacturer Defendants and the Distributor Defendants fail to monitor, detect, investigate, refuse to fill, and report orders of prescription opioids which they knew or should have known were likely to be diverted for nonmedical purposes?

e. Did the Defendants conduct the affairs of an enterprise through a pattern of racketeering activity?

f. Did the Defendants conspire to conduct the affairs of an enterprise through a pattern of racketeering activity?

g. Did the Manufacturer Defendants negligently manufacture, market, and sell opioids?

h. Did the Distributor Defendants negligently sell and distribute opioids?

i. Did the Manufacturer Defendants wantonly, recklessly, or with gross negligence manufacture, market, and sell opioids?

j. Did the Distributor Defendants wantonly, recklessly, or with gross negligence sell and distribute opioids?

k. Did the Defendants committee common-law fraud by making false representations of material fact and by concealing material facts about opioids?

l. Were Plaintiff and the Class members monetarily damaged as a direct and proximate result of the Defendants' acts and omissions?

427. Plaintiff's claims are typical of those of the Class, and are based on the same legal theories as those of the Class members. Plaintiff's claims and those of the Class members all arise from the same pattern or practice by the Defendants, set out above.

428. Plaintiff will fairly and adequately protect the interests of the members of the Class. Plaintiff has retained counsel who is highly experienced and competent in complex consumer class-action litigation, and Plaintiff and their counsel intend to prosecute this action vigorously. Neither Plaintiff nor their counsel has any interests that might cause them not to vigorously pursue this action. Plaintiff's interests are coextensive with those of the Class, and Plaintiff has no interests adverse to those of the Class members.

429. Plaintiff has made arrangements with their counsel for the discharge of their financial responsibilities to the Class. Plaintiff's counsel has the necessary financial resources to adequately and vigorously litigate this class action.

430. A class action is superior to all other available means for the fair and efficient adjudication of this controversy. It is desirable to concentrate the litigation of the claims in this forum, because the damages suffered by the individual Class members are relatively small compared to the burden and expense that would be entailed by individual litigation of their claims against Defendants. Moreover, the individual Class members are unlikely to be aware of their rights. Thus, it is unlikely that the Class members, on an individual basis, can obtain effective redress for the wrongs done to them. Additionally, the court system would be adversely affected by such individualized litigation. Individualized litigation would create the danger of inconsistent or contradictory judgments arising from the same set of facts. Individualized litigation would also increase delay and expense to all parties and the court system from the issues raised by this action. In contrast, the class-action device provides the benefit of adjudication of these issues in a single proceeding, with economies of scale and comprehensive supervision by a single court.

431. Plaintiff and their counsel are aware of no litigation concerning the controversy already begun by or against Class members. This also indicates that the Class members' interest in individually controlling the prosecution of separate actions is minimal.

CAUSES OF ACTION

COUNT I: RACKETEER INFLUENCED AND CORRUPT ORGANIZATIONS ACT 18 U.S.C. 1961, ET SEQ.

432. Plaintiff, individually and on behalf of the putative Class, realleges and incorporates by reference paragraphs 1-431 as if stated fully herein.

433. Plaintiff brings this Count against the following Defendants, as defined above: Purdue, Cephalon, Janssen, Endo, Mallinckrodt, Actavis, McKesson, Cardinal, and AmerisourceBergen (collectively, for purposes of this Count, the "RICO Defendants").

434. The RICO Defendants conducted and continue to conduct their business through legitimate and illegitimate means in the form of an association-in-fact enterprise and/or a legal entity enterprise. At all relevant times, the RICO Defendants were "persons" under 18 U.S.C. § 1961(3) because they are entities capable of holding, and do hold, "a legal or beneficial interest in property."

435. For efficiency and avoiding repetition, for purposes of this claim, Plaintiff incorporates by reference Paragraphs 324 through 355 concerning the Opioid Diversion Enterprise.

436. For efficiency and avoiding repetition, for purposes of this claim, Plaintiff incorporates by reference Paragraphs 356 through 366 concerning the Conduct of the Opioid Diversion Enterprise.

437. For efficiency and avoiding repetition, for purposes of this claim, Plaintiff incorporates by reference Paragraphs 367 through 422 concerning the Pattern of Racketeering Activity of the Opioid Diversion Enterprise.

438. Section 1962(c) of RICO makes it unlawful "for any person employed by or associated with any enterprise engaged in, or the activities of which affect, interstate or foreign commerce, to conduct or participate, directly or indirectly, in the conduct of such

enterprise's affairs through a pattern of racketeering activity or collection of unlawful debt." 18 U.S.C. § 1962(c); *United State v. Turkette*, 452 U.S. 576, 580 (1981).

439. The term "enterprise" is defined as including "any individual, partnership, corporation, association, or other legal entity, and any union or group of individuals associated in fact although not a legal entity." 18 U.S.C. § 1961(4); Turkette, 452 U.S. at 580; Boyle v. U.S., 556 U.S. 938, 944 (2009). The definition of "enterprise" in Section 1961(4) includes legitimate and illegitimate enterprises within its scope. Specifically, the section "describes two separate categories of associations that come within the purview of an 'enterprise' -- the first encompassing organizations such as corporations, partnerships, and other 'legal entities,' and the second covering 'any union or group of individuals associated in fact although not a legal entity. '" *Turkette*, 452 U.S. at 577. The second category is not a more generalized description of the first. Id.

440. For over a decade, the RICO Defendants aggressively sought to bolster their revenue, increase profit, and grow their share of the prescription painkiller market by unlawfully and surreptitiously increasing the volume of opioids they sold. However, the RICO Defendants are not permitted to engage in a limitless expansion of their market through the unlawful sales of regulated painkillers. As "registrants," the RICO Defendants operated and continue to operate within the "closed-system" created under the Controlled Substances Act, 21 U.S.C. § 821, et seq. (the "CSA"). The CSA restricts the RICO Defendants' ability to manufacture or distribute Schedule II substances like opioids by requiring them to: (1) register to manufacture or distribute opioids; (2) maintain effective controls against diversion of the controlled substances that they manufacturer or distribute; (3) design and operate a system to identify suspicious orders of controlled

substances, halt such unlawful sales, and report them to the DEA; and (4) make sales within a limited quota set by the DEA for the overall production of Schedule II substances like opioids.

441. The closed-system created by the CSA, including the establishment of quotas, was specifically intended to reduce or eliminate the diversion of Schedule II substances like opioids from "legitimate channels of trade" to the illicit market by controlling the quantities of the basic ingredients needed for the manufacture of [controlled substances]."

442. Finding it impossible to legally achieve their ever increasing sales ambitions, members of the Opioid Diversion Enterprise (as defined above) systematically and fraudulently violated their statutory duty to maintain effective controls against diversion of their drugs, to design and operate a system to identify suspicious orders of their drugs, to halt unlawful sales of suspicious orders, and to notify the DEA of suspicious orders. As discussed in detail below, through the RICO Defendants' scheme, members of the Opioid Diversion Enterprise repeatedly engaged in unlawful sales of painkillers which, in turn, artificially and illegally increased the annual production quotas for opioids allowed by the DEA. In doing so, the RICO Defendants allowed hundreds of millions of pills to enter the illicit market which allowed them to generate obscene profits.

443. Defendants' illegal scheme was hatched by an association-in-fact enterprise between the Manufacturer Defendants and the Distributor Defendants, and executed in perfect harmony by each of them. In particular, each of the RICO Defendants were associated with, and conducted or participated in, the affairs of the RICO enterprise (defined below and referred to collectively as the "Opioid Diversion Enterprise"), whose purpose was to engage in the unlawful sales of opioids, and deceive the public and

federal and state regulators into believing that the RICO Defendants were faithfully fulfilling their statutory obligations. The RICO Defendants' scheme allowed them to make billions in unlawful sales of opioids and, in turn, increase and/or maintain high production quotas with the purpose of ensuring unlawfully increasing revenues, profits, and market share. As a direct result of the RICO Defendants' fraudulent scheme, course of conduct, and pattern of racketeering activity, they were able to extract billions of dollars of revenue from the addicted American public, while entities like Plaintiff experienced tens of millions of dollars of injury caused by the reasonably foreseeable consequences of the prescription opioid addiction epidemic. As explained in detail below, the RICO Defendants' misconduct violated Section 1962(c) and Plaintiff is entitled to treble damages for their injuries under 18 U.S.C. § 1964(c).

444. Alternatively, the RICO Defendants were members of a legal entity enterprise within the meaning of 18 U.S.C. § 1961(4), through which the RICO Defendants conducted their pattern of racketeering activity in this jurisdiction and throughout the United States. Specifically, the Healthcare Distribution Alliance (the "HDA") is a distinct legal entity that satisfies the definition of a RICO enterprise. The HDA is a non-profit corporation formed under the laws of the District of Columbia and doing business in Virginia. As a non-profit corporation, HDA qualifies as an "enterprise" within the definition set out in 18 U.S.C. § 1961(4) because It is a corporation and a legal entity.

445. On information and belief, each of the RICO Defendants is a member, participant, and/or sponsor of the HDA and utilized the HDA to conduct the Opioid Diversion Enterprise and to engage in the pattern of racketeering activity that gives rise to the Count.

446. Each of the RICO Defendants is a legal entity separate and distinct from the HDA. And, the HDA serves the interests of distributors and Manufacturers beyond the RICO Defendants. Therefore, the HDA exists separately from the Opioid Diversion Enterprise, and each of the RICO Defendants exists separately from the HDA. Therefore, the HDA may serve as a RICO enterprise.

447. The legal and association-in-fact enterprises alleged in the previous and subsequent paragraphs were each used by the RICO Defendants to conduct the Opioid Diversion Enterprise by engaging in a pattern of racketeering activity. Therefore, the legal and association in- fact enterprises alleged in the previous and subsequent paragraphs are pleaded in the alternative and are collectively referred to as the "Opioid Diversion Enterprise. “The RICO Defendants' violations of law and their pattern of racketeering activity directly and proximately caused Plaintiff and the proposed Class members injury in their businesses, as described above in language expressly incorporated herein by reference.

448. Plaintiff's and the proposed Class members' injuries were proximately caused by Defendants' racketeering activities. But for the RICO Defendants' conduct, Plaintiff and the proposed Class members would not have incurred the monetary losses described above and expressly incorporated herein by reference.

449. Plaintiff's and the proposed Class members' injuries were directly caused by the RICO Defendants' racketeering activities.

450. Plaintiff seeks actual damages, treble damages, attorney's fees and all costs and expenses of suit and pre- and post-judgment interest.

COUNT II: RACKETEER INFLUENCED AND CORRUPT ORGANIZATIONS ACT 18 U.S.C. 1962(D), *ET SEQ.*

451. Plaintiff, individually and on behalf of the putative Class, realleges and incorporates by reference paragraphs 1-431 as if stated fully herein..

452. Plaintiff brings this Count against the following Defendants, as defined above: Purdue, Cephalon, Janssen, Endo, Mallinckrodt, Actavis, McKesson, Cardinal, and AmerisourceBergen (collectively, for purposes of this Count, the "RICO Defendants").

453. The RICO Defendants conducted and continue to conduct their business through legitimate and illegitimate means in the form of an association-in-fact enterprise and/or a legal entity enterprise. At all relevant times, the RICO Defendants were "persons" under 18 U.S.C. § 1961(3) because they are entities capable of holding, and do hold, "a legal or beneficial interest in property."

454. For efficiency and avoiding repetition, for purposes of this claim, Plaintiff incorporates by reference Paragraphs 324 through 355 concerning the Opioid Diversion Enterprise.

455. For efficiency and avoiding repetition, for purposes of this claim, Plaintiff incorporates by reference Paragraphs 365 through 366 concerning the Conduct of the Opioid Diversion Enterprise.

456. For efficiency and avoiding repetition, for purposes of this claim, Plaintiff incorporates by reference Paragraphs 367 through 422 concerning the Pattern of Racketeering Activity of the Opioid Diversion Enterprise.

457. Section 1962(c) of RICO makes it unlawful "for any person employed by or associated with any enterprise engaged in, or the activities of which affect, interstate or foreign commerce, to conduct or participate, directly or indirectly, in the conduct of such

enterprise's affairs through a pattern of racketeering activity or collection of unlawful debt." 18 U.S.C. § 1962(c); *United State v. Turkette*, 452 U.S. 576, 580 (1981).

458. The term "enterprise" is defined as including "any individual, partnership, corporation, association, or other legal entity, and any union or group of individuals associated in fact although not a legal entity." 18 U.S.C. § 1961(4); Turkette, 452 U.S. at 580; Boyle v. U.S., 556 U.S. 938, 944 (2009). The definition of "enterprise" in Section 1961(4) includes legitimate and illegitimate enterprises within its scope. Specifically, the section "describes two separate categories of associations that come within the purview of an 'enterprise' -- the first encompassing organizations such as corporations, partnerships, and other 'legal entities,' and the second covering 'any union or group of individuals associated in fact although not a legal entity. '" *Turkette*, 452 U.S. at 577. The second category is not a more generalized description of the first. Id.

459. For over a decade, the RICO Defendants aggressively sought to bolster their revenue, increase profit, and grow their share of the prescription painkiller market by unlawfully and surreptitiously increasing the volume of opioids they sold. However, the RICO Defendants are not permitted to engage in a limitless expansion of their market through the unlawful sales of regulated painkillers. As "registrants," the RICO Defendants operated and continue to operate within the "closed-system" created under the Controlled Substances Act, 21 U.S.C. § 821, et seq. (the "CSA"). The CSA restricts the RICO Defendants' ability to manufacture or distribute Schedule II substances like opioids by requiring them to: (1) register to manufacture or distribute opioids; (2) maintain effective controls against diversion of the controlled substances that they manufacturer or distribute; (3) design and operate a system to identify suspicious orders of controlled

substances, halt such unlawful sales, and report them to the DEA; and (4) make sales within a limited quota set by the DEA for the overall production of Schedule II substances like opioids.

460. The closed-system created by the CSA, including the establishment of quotas, was specifically intended to reduce or eliminate the diversion of Schedule II substances like opioids from "legitimate channels of trade" to the illicit market by controlling the quantities of the basic ingredients needed for the manufacture of [controlled substances]."

461. Finding it impossible to legally achieve their ever increasing sales ambitions, members of the Opioid Diversion Enterprise (as defined above) systematically and fraudulently violated their statutory duty to maintain effective controls against diversion of their drugs, to design and operate a system to identify suspicious orders of their drugs, to halt unlawful sales of suspicious orders, and to notify the DEA of suspicious orders. As discussed in detail below, through the RICO Defendants' scheme, members of the Opioid Diversion Enterprise repeatedly engaged in unlawful sales of painkillers which, in turn, artificially and illegally increased the annual production quotas for opioids allowed by the DEA. In doing so, the RICO Defendants allowed hundreds of millions of pills to enter the illicit market which allowed them to generate obscene profits.

462. Defendants' illegal scheme was hatched by an association-in-fact enterprise between the Manufacturer Defendants and the Distributor Defendants, and executed in perfect harmony by each of them. In particular, each of the RICO Defendants were associated with, and conducted or participated in, the affairs of the RICO enterprise (defined below and referred to collectively as the "Opioid Diversion Enterprise"), whose purpose was to engage in the unlawful sales of opioids, and deceive the public and

federal and state regulators into believing that the RICO Defendants were faithfully fulfilling their statutory obligations. The RICO Defendants' scheme allowed them to make billions in unlawful sales of opioids and, in turn, increase and/or maintain high production quotas with the purpose of ensuring unlawfully increasing revenues, profits, and market share. As a direct result of the RICO Defendants' fraudulent scheme, course of conduct, and pattern of racketeering activity, they were able to extract billions of dollars of revenue from the addicted American public, while entities like Plaintiff experienced tens of millions of dollars of injury caused by the reasonably foreseeable consequences of the prescription opioid addiction epidemic. As explained in detail below, the RICO Defendants' misconduct violated Section 1962(c) and Plaintiff is entitled to treble damages for their injuries under 18 U.S.C. § 1964(c).

463. Alternatively, the RICO Defendants were members of a legal entity enterprise within the meaning of 18 U.S.C. § 1961(4), through which the RICO Defendants conducted their pattern of racketeering activity in this jurisdiction and throughout the United States. Specifically, the Healthcare Distribution Alliance (the "HDA") is a distinct legal entity that satisfies the definition of a RICO enterprise. The HDA is a non-profit corporation formed under the laws of the District of Columbia and doing business in Virginia. As a non-profit corporation, HDA qualifies as an "enterprise" within the definition set out in 18 U.S.C. § 1961(4) because It is a corporation and a legal entity.

464. On information and belief, each of the RICO Defendants is a member, participant, and/or sponsor of the HDA and utilized the HDA to conduct the Opioid Diversion Enterprise and to engage in the pattern of racketeering activity that gives rise to the Count.

465. Each of the RICO Defendants is a legal entity separate and distinct from the HDA. And, the HDA serves the interests of distributors and Manufacturers beyond the RICO Defendants. Therefore, the HDA exists separately from the Opioid Diversion Enterprise, and each of the RICO Defendants exists separately from the HDA. Therefore, the HDA may serve as a RICO enterprise.

466. The legal and association-in-fact enterprises alleged in the previous and subsequent paragraphs were each used by the RICO Defendants to conduct the Opioid Diversion Enterprise by engaging in a pattern of racketeering activity. Therefore, the legal and association in- fact enterprises alleged in the previous and subsequent paragraphs are pleaded in the alternative and are collectively referred to as the "Opioid Diversion enterprise." The RICO Defendants' violations of law and their pattern of racketeering activity directly and proximately caused Plaintiff and the proposed Class members injury in their businesses, as described above in language expressly incorporated herein by reference.

467. Plaintiff's and the proposed Class members' injuries were proximately caused by Defendants' racketeering activities. But for the RICO Defendants' conduct, Plaintiff and the proposed Class members would not have incurred the monetary losses described above and expressly incorporated herein by reference.

468. Defendants conspired to violate Section 1962(c), as alleged more fully above, by conducting the affairs of the Opioid Diversion Enterprise through a pattern of racketeering activity, as incorporated by reference The RICO Defendants' violations of law and their pattern of racketeering activity directly and proximately caused Plaintiff's

and the proposed Class members' injury in their businesses, as described above in language expressly incorporated herein by reference.

469. Plaintiff brings this claim against all RICO Defendants. At all relevant times, the RICO Defendants were associated with the Opioid Diversion Enterprise and agreed and conspired to violate 18 U.S.C. § 1962(c), that is, they agreed to conduct and participate, directly and indirectly, in the conduct of the affairs of the Opioid Diversion Enterprise through a pattern of racketeering activity in violation of 18 U.S.C. § 1962(d). Under Section 1962(d) it is unlawful for "any person to conspire to violate" Section 1962(c), among other provisions. 18 U.S.C. § 1962(d).

470. Plaintiff's and the proposed Class members' injuries were directly caused by the RICO Defendants' racketeering activities.

471. Plaintiff seeks actual damages, treble damages, attorney's fees and all costs and expenses of suit and pre- and post-judgment interest.

COUNT III: NEGLIGENCE

480. Plaintiff, individually and on behalf of the putative Class, realleges and incorporates by reference paragraphs 1-232 and 423-431 as if stated fully herein.

481. Under State law, to establish actionable negligence, one must show the existence of a duty, a breach of that duty, and injury resulting proximately therefrom. All such essential elements exist here.

482. Each Defendant had duties to exercise reasonable, or due, care in marketing, promoting, selling, and distributing highly dangerous Schedule II opioid drugs.

483. Defendants' duties are set out as a matter of law, to monitor, report and prevent against diversion.

484. Each Defendant breached its aforesaid duties by its conduct previously specified herein; namely the false and misleading marketing promotion, sale and distribution of opioid drugs.

485. Manufacturer Defendants breached their duties, as detailed above, when they:

e. misrepresented that opioids improve function;

f. misrepresented that opioids are safe and effective for long-term use;

g. concealed the link between long-term use of opioids and addiction;

h. misrepresented that addiction risk can be managed;

i. masked the signs of addiction by calling them "pseudoaddiction";

j. falsely claimed withdrawal is easily managed;

k. misrepresented or omitted the greater dangers from higher doses of opioids;

l. deceptively minimized the adverse effects of opioids and overstated the risks of NSAIDs; and

m. failing to monitor, report, and halt suspicious orders of opioids based on chargeback data.

486. The Distributor Defendants breached their duty to exercise due diligence to avoid filling suspicious orders that might be diverted into channels other than legitimate medical, scientific and industrial channels.

487. Each Defendant owed its aforesaid duties to Plaintiff and the members of the proposed Class because the injuries alleged herein were foreseeable by the Defendants.

488. The fact that Plaintiff and the class he seeks to represent would have to provide medical services for opioid addicted patients was both the foreseeable and intended consequence of Defendants' marketing scheme. Defendants set out to change the medical and general

consensus supporting chronic opioid therapy, encouraging doctors to prescribe, long- term prescriptions of opioids to treat chronic pain despite the absence of genuine evidence supporting chronic opioid therapy and the contrary evidence regarding the significant risks and limited benefits from long-term use of opioids.

489. Because opioids are very dangerous and highly addictive drugs, it was foreseeable to Defendants that the opioid epidemic would result in a corresponding epidemic of patients with opioid conditions at emergency rooms. It was also foreseeable to Defendants that Plaintiff and the Class members would suffer the aforesaid monetary losses because of the opioid epidemic, since emergency room physicians typically are not reimbursed for their treatment of uninsured patients and receive only partial reimbursement for their treatment of patients with health insurance or government assistance.

490. Plaintiff and the Class members incur partial monetary losses for patients with health insurance, and total monetary losses for uninsured patients, in the treatment of patients with opioid conditions. These patients would not have presented to Plaintiff and the Class members, and would not have had opioid conditions, but for the opioid epidemic created and engineered by Defendants. Accordingly, Plaintiff's and the Class members' aforesaid monetary losses are the direct and proximate result of Defendants' acts and omissions previously specified herein.

491. Plaintiff and the members of the proposed Class seek compensatory damages for their monetary losses previously specified herein, plus interest and the costs of this action.

COUNT IV: WANTONNESS, RECKLESSNESS, AND GROSS NEGLIGENCE

492. Plaintiff, individually and on behalf of the putative Class, realleges and incorporates by reference paragraphs 1-232 and 423-431 as if stated fully herein.

493. Defendants' aforesaid acts and omissions were done and omitted knowing that injury to Plaintiff and the Class members would likely or probably result; were done or omitted with a reckless or conscious disregard of the rights of Plaintiff and the Class members; were done or omitted without the exercise of even a slight degree of care; were done or omitted with conscious indifference to the consequences; and/or constituted a substantial deviation from the standard of care applicable.

494. Each Defendant had duties to exercise reasonable, or due, care in marketing, promoting, selling, and distributing highly dangerous Schedule II opioid drugs.

495. Defendants' duties are set out as a matter of law, to monitor, report and prevent against diversion.

496. Each Defendant breached its aforesaid duties by its conduct previously specified herein; namely the false and misleading marketing promotion, sale and distribution of opioid drugs.

497. Manufacturer Defendants breached their duties, as detailed above, when they:

a. misrepresented that opioids improve function;

b. misrepresented that opioids are safe and effective for long-term use;

c. concealed the link between long-term use of opioids and addiction;

d. misrepresented that addiction risk can be managed;

e. masked the signs of addiction by calling them "pseudoaddiction";

f. falsely claimed withdrawal is easily managed;

g. misrepresented or omitted the greater dangers from higher doses of opioids;

h. deceptively minimized the adverse effects of opioids and overstated the risks of NSAIDs; and

i. failing to monitor, report, and halt suspicious orders of opioids based on chargeback data.

498. The Distributor Defendants breached their duty to exercise due diligence to avoid filling suspicious orders that might be diverted into channels other than legitimate medical, scientific and industrial channels.

499. Each Defendant owed its aforesaid duties to Plaintiff and the members of the proposed Class because the injuries alleged herein were foreseeable by the Defendants.

500. The fact that Plaintiff and the class he seeks to represent would have to provide medical services for opioid addicted patients was both the foreseeable and intended consequence of Defendants' marketing scheme. Defendants set out to change the medical and general consensus supporting chronic opioid therapy, encouraging doctors to prescribe, long- term prescriptions of opioids to treat chronic pain despite the absence of genuine evidence supporting chronic opioid therapy and the contrary evidence regarding the significant risks and limited benefits from long-term use of opioids.

501. Because opioids are very dangerous and highly addictive drugs, it was foreseeable to Defendants that the opioid epidemic would result in a corresponding epidemic of patients with opioid conditions at emergency rooms. It was also foreseeable to Defendants that Plaintiff and the Class members would suffer the aforesaid monetary losses because of the opioid epidemic, since emergency room physicians typically are not reimbursed for their treatment of uninsured patients and receive only partial reimbursement for their treatment of patients with health insurance or government assistance.

502. Plaintiff and the Class members incur partial monetary losses for patients with health insurance, and total monetary losses for uninsured patients, in the treatment of patients

with opioid conditions. These patients would not have presented to Plaintiff and the Class members, and would not have had opioid conditions, but for the opioid epidemic created and engineered by Defendants. Accordingly, Plaintiff's and the Class members' aforesaid monetary losses are the direct and proximate result of Defendants' acts and omissions previously specified herein.

503. As a direct and proximate result of Defendants' wantonness, recklessness, or gross negligence, Plaintiff and the Class members were monetarily damaged as aforesaid.

504. Plaintiff seeks compensatory and punitive damages, plus the costs of this action.

COUNT V: COMMON LAW FRAUD

505. Plaintiff, individually and on behalf of the putative Class, realleges and incorporates by reference paragraphs 1-232 and 423-431 as if stated fully herein.

506. As alleged herein, Manufacturer Defendants intentionally made false representations and concealed material facts about opioids, including but not limited to:

a. misrepresented that opioids improve function;

b. misrepresented that opioids are safe and effective for long-term use;

c. concealed the link between long-term use of opioids and addiction;

d. misrepresented that addiction risk can be managed;

e. masked the signs of addiction by calling them “pseudoaddiction”;

f. falsely claimed withdrawal is easily managed;

g. misrepresented or omitted the greater dangers from higher doses of opioids;

h. and deceptively minimized the adverse effects of opioids and overstated the risks of NSAIDs.

507. Manufacturer Defendants made misrepresentations and failed to disclose material facts to physicians and consumers throughout the United States, to induce the physicians to prescribe and administer, and consumers to purchase and consume, opioids as set forth herein.

508. The Distributor Defendants refuse to abide by the duties imposed by federal law which are required to legally acquire and maintain a license to distribute prescription opiates. The unlawful conduct by the Distributor Defendants is purposeful and intentional. The Distributor Defendants' repeated shipments of suspicious orders, over an extended period of time, in violation of public safety statutes, and without reporting the suspicious orders to the relevant authorities.

509. Distributor Defendants made misrepresentations and failed to disclose material facts to authorities throughout the United States, to induce the prescription, administration and consumption of opioids as set forth herein.

510. Defendants' false representations and omissions were material, and were made and omitted intentionally or recklessly.

511. Defendants intended that physicians and consumers would rely upon their misrepresentations and omissions.

512. Physicians and consumers reasonably relied on Defendants' misrepresentations and omissions. Physicians prescribed and administered, and consumers purchased and consumed, opioids as set forth herein.

513. Because of physicians' and consumers' reliance on Defendants' misrepresentations and omissions of material fact, Plaintiff and the Class members have suffered monetary

damages as aforesaid. Plaintiff seeks compensatory and punitive damages, plus the costs of this action.

514. Defendants' marketing of opioids caused Plaintiff and the putative class he seeks to represent to diagnose, care for and treat opioid addicted patients who presented with opioid addicted symptoms. All of these medical services provided by Plaintiff were caused by Defendants' fraudulent marketing and scheme. Defendants should be held responsible for all economic damages suffered by Plaintiff and the putative class he seeks to represent. Plaintiff is obligated to cover medically necessary and reasonably required care; he had no choice but to provide these services although often he was not paid or was paid substantially less than market rates.

515. The fact that Plaintiff and the class he seeks to represent would have to provide medical services for opioid addicted patients was both the foreseeable and intended consequence of Defendants' fraudulent marketing scheme. Defendants set out to change the medical and general consensus supporting chronic opioid therapy with the intention of encouraging doctors to prescribe, long- term prescriptions of opioids to treat chronic pain despite the absence of genuine evidence supporting chronic opioid therapy and the contrary evidence regarding the significant risks and limited benefits from long-term use of opioids.

516. Because opioids are very dangerous and highly addictive drugs, it was foreseeable to Defendants that the opioid epidemic would result in a corresponding epidemic of patients with opioid conditions in emergency rooms. It was also foreseeable to Defendants that Plaintiff and the Class members would suffer the aforesaid monetary losses because of the opioid epidemic, since emergency room physicians typically are not reimbursed for their

treatment of uninsured patients and receive only partial reimbursement for their treatment of patients with health insurance.

517. Defendants' misrepresentations were material to, and influenced, the opioid-addicted patients presented to Plaintiff and the class he seeks to represent. In the first instance, Plaintiff would not have been presented with, or required to diagnose, care and treat these opioid-addicted patients, but for Defendants' fraudulent and deceptive marketing. Second, Plaintiff has demonstrated that Defendants' marketing is material by setting forth in detail Defendants' wrongful acts.

518. Plaintiff and the members of the proposed Class seek compensatory damages for their monetary losses previously specified herein, plus interest and the costs of this action.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff individually and on behalf of all others similarly situated, ask that the Court:

(a) Certify the Class proposed herein;

(b) Appoint Plaintiff as representative of the Class;

(c) Appoint Plaintiff's counsel as attorneys for the Class;

(d) Enter judgment awarding Plaintiff and the Class members monetary damages, compensatory in nature, on their negligence claim;

(e) Enter judgment awarding Plaintiff and the Class members monetary damages, compensatory and punitive, on their claims for wanton, reckless, and grossly negligent conduct, and on their claims for fraud;

(f) Enter judgment awarding Plaintiff and the Class members treble damages on their RICO claims;

(g) Award Plaintiff and the class members prejudgment interest and post-judgment interest as provided by law;

(h) Award Plaintiff and the Class members a reasonable attorney's fee and costs; and

(i) Provide such further relief as may be just and proper.

JURY DEMAND

Plaintiff, individually and on behalf of the Class members, demand a trial by jury on all issues so triable.

Respectfully Submitted,

DATED: July 25th, 2018

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